Consumed During a Field Service Visit

OTI Scan 3000

B/A and UBM Ophthalmic Ultrasound

User Manual

U.S. Federal Law requires that this device be used only by or under the supervision of a physician.

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UMN-000002 Rev. 2

Regulatory Notices

U.S. Federal Law requires that this device be used only by or under the supervision of a physician.

This device has been found to operate within the limits for a Class A digital device, and is not intended for use in a residential environment.

This is a Class IIa medical device.

Electrical Safety: Class II Type B

Manufacturer:

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Warranty Information

OPTOS warrants its products are free of defects of labor and material for two years for electronics, 1 year for probes. Associated computer systems carry a 1-year manufacturer's warranty; extended warranties are optionally available.

The following items are not covered:

- Physical damage to the unit or probes due to misuse or shock
- Damage or data loss due to power failures or fluctuations. The use of a line-interactive UPS is recommended to avoid these types of failures.
- Loss or corruption of data or software due to user error or the installation or use of any third-party hardware or software.
- Damage to transducers caused by autoclaving or exposure to excessive heat.
- Repairs not covered by warranty will be invoiced on the basis of parts and labour. At OPTOS' discretion, the damaged component may be exchanged at a flat rate.

Networking

OPTOS does not provide support for the operation of its products in a network environment. Connection to and operation on any network is entirely the responsibility of the user. Where installation or use of any network hardware or software interferes with the normal operation of the OPTOS product, that product must be returned to normal operation at the user's expense. When the connection of an OPTOS product to or installation of OPTOS-supplied software on, a network interferes with the operation of the network, the product must be removed from the network; alternatively, the problem may be resolved by the user in cooperation with the network owner, at their expense.

Third-Party Software

OPTOS does not provide support for the use or installation of any software obtained from a third party on its products, including, but not limited to, operating system upgrades and device drivers. When software not supplied by OPTOS interferes with the operation of the system, the product will be returned to its original condition at the user's expense.

OPTOS may occasionally furnish to users software not directly related to the functioning of its products. Such software is supplied as is, without warranty of any kind, and the availability of support for such software is at OPTOS' sole discretion.

Standards and Regulations

- FDA Approved # K092837
- This device is a Class IIa medical device as defined by the European Medical Device Directive (MDD)
- The device complies with the EC Medical Device Directive 93/42/EEC

CE 0470

Warnings and Cautions

Warning:

Switching on a cold instrument near 0° Celsius will permanently damage it. Let the instrument reach a normal room temperature for half a day to allow the internal elements to warm up and to avoid any thermal shock hazards when switched on. The cover will quickly reach room temperature, but not the internal circuitry.

Warning:

Unit is approved for operation only with the included power supply.

Warning:

Disconnect AC POWER before cleaning the case.

Warning:

Data will be saved under the same patient name until another has been selected.

Warning:

The transducers are fragile. Dropping or striking any probe can cause it to malfunction; handle all probes with care. If a probe should be dropped, inspect it carefully for chips and cracks, and make a test scan on a known object.

Warning:

This device is not intended for foetal use.

Caution

The console must not be disconnected from the computer while the system is running.

Caution:

The probe must be connected or disconnected only when the unit is switched OFF.

Warning:

Never autoclave a transducer or expose it to high heat.

Caution:

Follow the instructions included in this manual for disinfecting the transducer after each use.

Caution:

Applying excessive pressure to the probe will cause discomfort for the patient and distort the eye, resulting in incorrect measurements.

Caution: Choosing the wrong vitreous material will create serious errors in the axial length and calculation result in Biometry mode.

Introduction

This User's Manual describes the OTI Scan 3000 B, A and UBM system hardware and software. This page is a brief outline of the entire system. The functions described will not be available on every system: the selection depends on the system configuration.

The software uses a tabbed interface: the user can select any of the primary functional modules at any time by clicking on the tab for that function at the top of the screen. When there are several major components in a function, these are presented as tabs below the principal tab bar.

The opening screen is generally the Patient Data screen. The operator is not required to identify the patient before starting the examination; this can be done at any time during the exam, and, if no patient has been selected when "Save" is clicked, the operator is automatically taken into the database to select the appropriate patient record or create a new one. **Warning:** the same patient will be used for all saves until another has been selected.

The patient information screen has been organised to display full information and a list of saved examinations for the selected patient, summary information about the images is displayed, including any notes on probe orientation that were recorded at the time the image was captured and saved. When an exam is selected, a simplified view is presented, so that the user can review it. It is possible to copy and delete saved examinations one at a time.

The printing system has been designed to use the default printer and provide access to the control functions available from the printer drivers. Curves are printed in black on white, reducing ink consumption.

Chapter 1

Characteristics

1 Description

The OTI Scan 3000 modular ultrasound system is an ultrasonic diagnostic system intended to be used for ophthalmic applications.

Scans can be made in Immersion Mode or by placing the probe directly on the eye. UBM scans require the use of an immersion cup.

The OTI Scan 3000 software runs on Windows, and uses the features of the Windows interface to direct the operation of the system and maintain patient records, permitting a user-friendly environment for clinical applications.

2 System Components

Depending on the configuration of the system, the OTI Scan 3000 system consists of the B-Scan ultrasound unit, which contains the UBM/B-Scan ultrasonic pulsar/receiver and scan converter, and/or an A-Scan ultrasound unit, which contains the A-Scan ultrasonic pulsar/receiver and scan converter. The system may include a focussed B-scan probe operating at 10MHz, focussed biometry probe operating at 13 MHz, diagnostic A-scan, and/or focussed 35 or 50MHz high frequency UBM probes.

3 Application

To make a measurement, the operator first displays the acquisition screen, and follows the instructions for its various controls. The probe is applied to the patient's eye directly or using an immersion cup. For biometry, there are two modes of operation, automatic and manual. In automatic mode the system identifies the critical structures in the eye and makes the measurements. In manual operation the operator must freeze an image and then select the points for the measurements. There are optional settings for particular cases such as dense cataracts or silicone-filled eyes.

4 Specifications

a. Dimensions

i. Console

1. 195 mm (l) x 116 mm (d) x 44 mm (h)
2. Weight: 0.6 kg

b. Power Supply

i. Console

1. Medical Grade Power Supply
2. Input Voltage range: 100-240V AC
3. Output Voltage: 12V DC
4. Frequency: 50/60Hz
5. AC power consumption: 18VA @ 120V
6. DC power consumption: 13W

c. Operating conditions

i. Temperature:

1. Operating = 19 degrees to 35 degrees C (32 to 95 F)
2. Storage= -40 to 65 C (-40 to 149 F)

ii. Relative humidity:

1. Operating = 10% to 90% (non-condensing)
2. Storage: 5% to 95% (non-condensing)

d. Probes

i. Biometry

1. Reference: US-PRO-A
2. Frequency: 13MHz
3. Focal Length: 23mm
4. Operating mode: Pulsed
5. PRF: 10Hz
6. Active diameter: 3.5mm
7. Active surface: 9.6mm2
8. Axial resolution: 0.12mm
9. Minimum distance measured: 12mm
10. Maximum distance measured: 37mm
11. Acquisition
    i. Horizontal resolution: 1020 points
    ii. Vertical resolution: 256 points
    iii. Linear resolution: 0.052mm

ii. B Scan

1. Reference: US-PRO-10
2. Frequency: 10MHz
3. Focal Length: 23mm
4. Operating mode: Pulsed
5. PRF: 3840 Hz

6. Active diameter: 7mm
7. Active surface: 154mm2
8. Axial resolution: 0.15mm

iii. Hi-Res B Scan

1. Reference: US-PRO-20
2. Frequency: 20MHz
3. Focal Length: mm
4. Operating mode: Pulsed
5. PRF: 3840 Hz
6. Active diameter: 7mm
7. Active surface: 154mm2
8. Axial resolution: 0.09mm

iv. High Frequency

1. Reference: US-PRO-35, US-PRO-50
2. Frequency: 35 or 50MHz
3. Focal Length: 13mm
4. Operating mode: Pulsed
5. PRF: 3072 Hz
6. Active diameter: 7mm
7. Active surface: 154mm^2
8. Axial resolution: 0.0219 or 0.0153mm
9. Scan depth: 15mm

e. Acquisition

i. Vertical resolution: 1020 points

ii. Horizontal resolution: 256 lines

iii. Linear resolution: up to 14.6μm

f. Accuracy

i. Measurement accuracy depends on the probe frequency and the technique employed. Maximum accuracy equals the axial resolution, assuming no errors in technique

ii. IOL powers are displayed in increments of .25D, with refractive errors estimated to .01D. For SRK II, a .2mm error in axial length yields a .5D error in calculated refraction; for other formulas, a .5D error corresponds to a .15mm error in the axial length.

5 ALARA Section and Emissions

Probe: Material: PZT

Nominal Center Frequency 13 MHz

Pulse repetition frequency: Hz

Type: A-scan, Energy emitted in bursts. Measurement must be repeated for new burst.

Ultrasonic Intensities in tissue: *

I_{SPTA}, 0.0285mW/cm^2.

I_{SPPA}, 6.76W/cm^2.

Mechanical Index 0.13

Ultrasonic power: 2.75μW

* At measured transducer focus (0.5 centimeters from probe tip)

The energy will always be attenuated by the tissue between the transducer and the focus when used as recommended. The values presented here are the values at the focal point, the point of maximum intensity.

It is not possible to vary the output energy of the transducer. However, to minimize exposure, measurements should be kept as short as possible.

If more accuracy is desired, the intensity in the body at any transducer point may be calculated according to the formula recommended by the FDA:

$I_t = I_w \exp(-0.069fz)$,

where I_t = is the estimated in situ intensity, I_w is the measured intensity in water at the focus of the transducer (indicated in the above chart), f is the ultrasonic frequency in megahertz, and z is the distance from the face of the probe to the transducer focus in centimeters, which is the point of measurement. For this device, f = 12 and z = .500. This formula was also used to calculate the derated values shown above.

Transducer parameters show considerable variation from transducer to transducer. The measured and calculated values shown above were those for an actual transducer, whose values deviated slightly from the values in the specification given, and whose values are likely to be different from the transducer with your system. However, the values in the specification should give results that are accurate enough for any practical purpose, since the intensities are very low.

One should always minimize exposure by limiting the ultrasonic transmission to as short periods as possible.

Velocity of sound used by system: (values for different eyes)

Aqueous	1532
Vitreous	1532
Silicone Oil	990
Natural lens	1641
Silicone IOL	980
PMMA IOL	2718
Acrylic IOL	2120

A -Probe

Table 5-3
Acoustic Output Reporting Table for Track 1.
Non-Auto scanning Mode
Transducer Model: 2020-1368 **Operating Mode:** A-Mode
Application(s): Ophthalmic

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Maximum Value			0.13	0.0285	6.76
Associated Acoustic Parameters	$P_{r.3}$ (MPa)		0.45	-	-
	W_0 (μW)		-	2.75	2.75
	f_c (MHz)		11.46	11.46	11.46
	z_{sp} (cm)		0.52	0.52	0.52
	Beam dimensions	x_{-6} (cm)	-	0.232	0.232
		y_{-6} (cm)	-	0.340	0.340
	PD (μS)		0.08	-	0.08
	PRF* (Hz)		50	-	50
	EBD	Az (cm)	-	0.35	-
		Ele. (cm)	-	0.35	-
Operating Control Conditions					

10 MHz Transducer:

Acoustic Output Reporting Table for Track 1. Autoscanning Mode

Transducer Model: 10MHz (S/N 20802) **Operating Mode:** B-Mode

Application: Ophthalmic

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value				0.162	0.219	8.61
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.482		
	W_0		(mW)		0.106	0.106
	f_c		(MHz)	8.84	8.84	8.84
	z_{sp}		(cm)	1.80		1.80
	Beam dimensions	x_{-6}	(cm)			0.0919
		y_{-6}	(cm)			0.0884
	PD		(μsec)	0.153		0.153
	PRF		(Hz)	3840		3840
	EDS	Az.	(cm)		1.200	
		Ele.	(cm)		0.600	
Operating Control Conditions	50 degree scan angle					
	10 Hz scan rate					
	384 lines per scan					

20 MHz Transducer:

Acoustic Output Reporting Table for Track 1. Autoscanning Mode

Transducer Model: 20 MHz B-Mode (S/N 22600)
Operating Mode: B-Mode
Application: Ophthalmic

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value				0.138	0.144	10.1
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.517		
	W_0		(mW)		0.0697	0.0697
	f_c		(MHz)	14.0	14.0	14.0
	z_{sp}		(cm)	1.70		1.70
	Beam dimensions	x-ϵ	(cm)			0.0637
		y-ϵ	(cm)			0.0613
	PD		(µsec)	0.116		0.116
	PRF		(Hz)	3840		3840
	EDS	Az.	(cm)		1.200	
		Ele.	(cm)		0.600	
Operating Control Conditions	50 degree scan angle					
	10 Hz scan rate					
	384 lines per scan					

35 MHz Transducer:

Acoustic Output Reporting Table for Track 1. Autoscanning Mode

Transducer Model: 35 MHz B-Mode (S/N 35-00894)
Operating Mode: B-Mode
Application: Ophthalmic

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value				0.0720	0.0340	6.52
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.319		
	W_0		(mW)		5.34E-3	5.34E-3
	f_c		(MHz)	19.4	19.4	19.4
	z_{sp}		(cm)	1.00		1.00
	Beam dimensions	x_{-6}	(cm)			0.0432
		y_{-6}	(cm)			0.0397
	PD		(μsec)	0.0350		0.0350
	PRF		(Hz)	3070		3070
	EDS	Az.	(cm)		1.330	
		Ele.	(cm)		0.700	
Operating Control Conditions	18 degree scan angle					
	8 Hz scan rate					
	384 lines per scan					

50 MHz Transducer:

Acoustic Output Reporting Table for Track 1. Autoscanning Mode

Transducer Model: 50MHz B-Mode (S/N 50-01084)
Operating Mode: B-Mode
Application: Peripheral

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value				0.0270	8.38E-3	1.81
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.134		
	W_0		(mW)		1.42E-3	1.42E-3
	f_c		(MHz)	25.1	25.1	25.1
	z_{sp}		(cm)	1.05		1.05
	Beam dimensions	x_{-6}	(cm)			0.0327
		y_{-6}	(cm)			0.0360
	PD		(µsec)	0.0410		0.0410
	PRF		(Hz)	3070		3070
	EDS	Az.	(cm)		1.330	
		Ele.	(cm)		0.700	
Operating Control Conditions	18 degree scan angle					
	8 Hz scan rate					
	384 lines per scan					

STANDARD SYMBOLS

Attention, consult accompanying documents.

Dangerous voltage

Symbol type B equipment

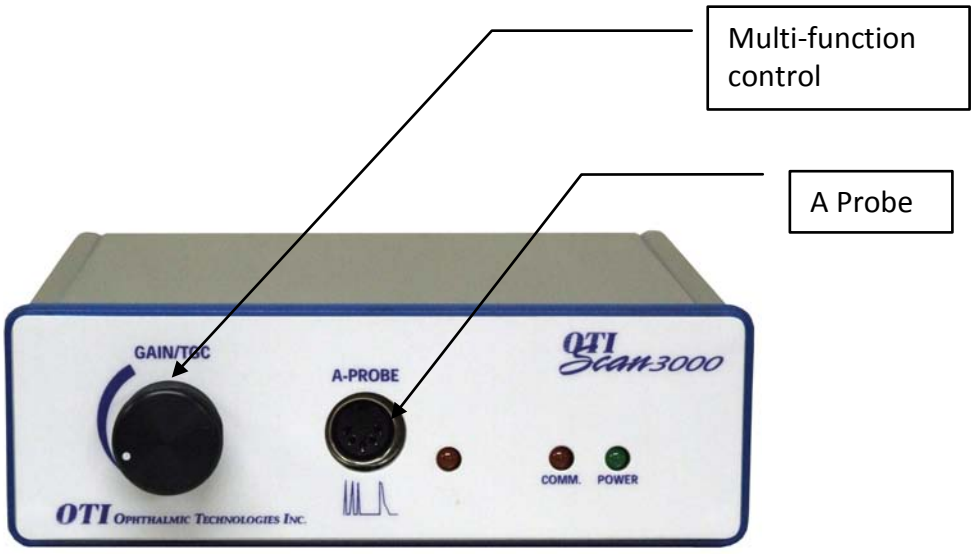
Classe 1

Accessible conductive parts are connected to earth

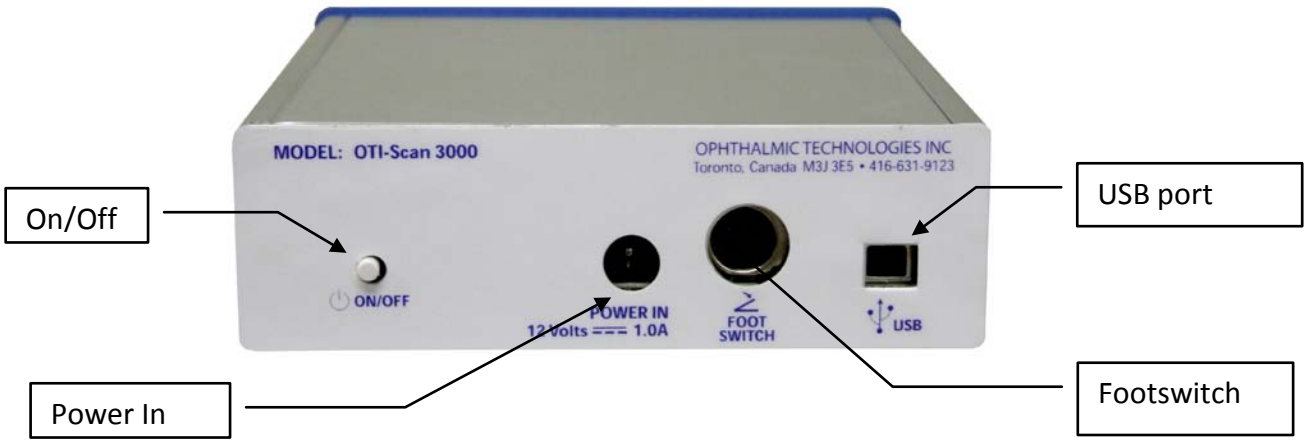
Equipotential point

6 DESCRIPTION and CONNECTIONS

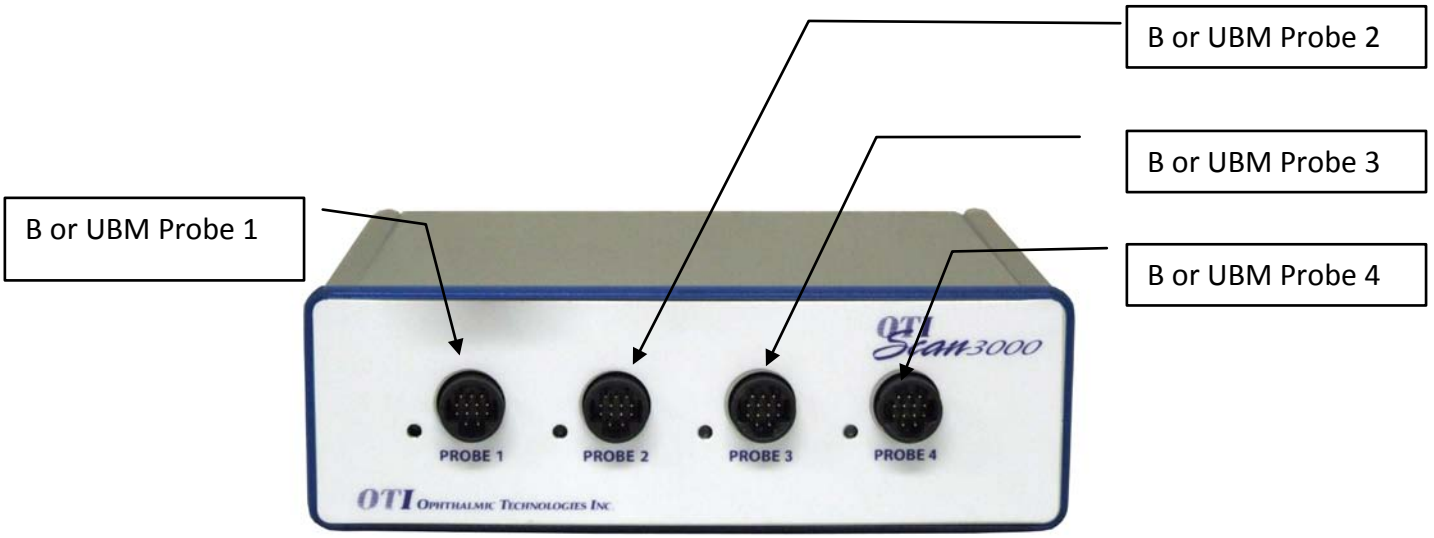
A. Front Panel A-Scan



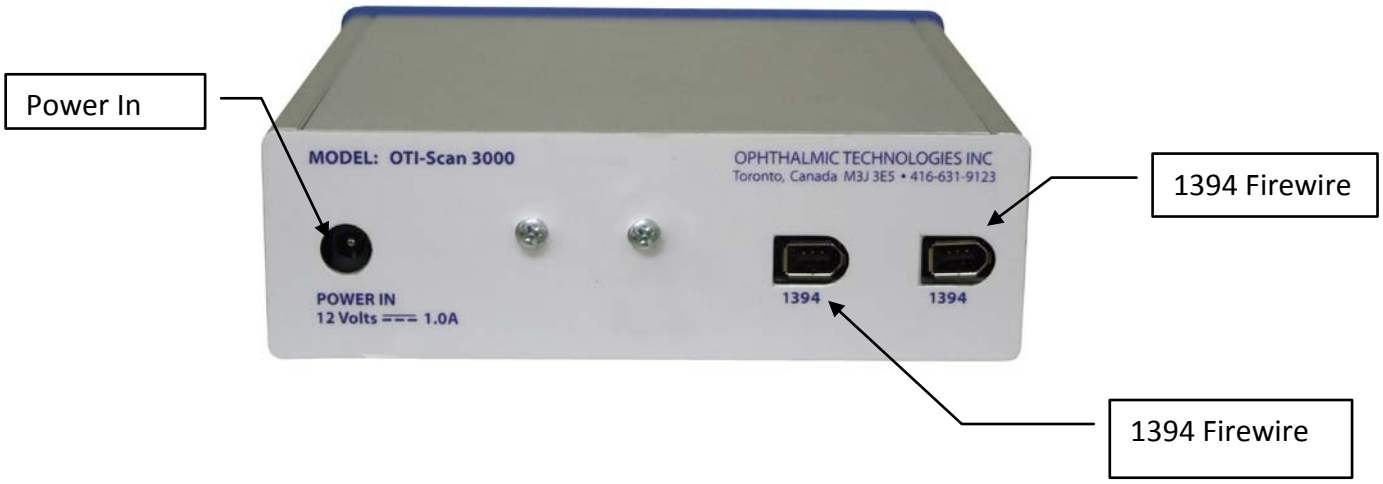
B. Rear Panel A-Scan



C. Front Panel B-Scan



D. Rear Panel B-Scan



E. Probes and Accessories

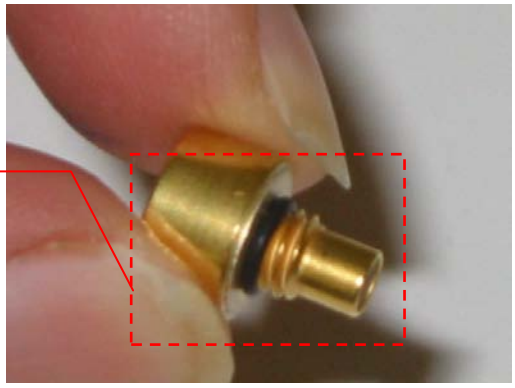
10MHz & 20MHz B-Probe

A/Biometry Probe

35 and 50 MHz UBM Probes

The transducer is removable for storage and cleaning.

Do not store the probe with the transducer attached.



Power Supply

B Probe Cable

Probe Holder

A-Scan Footswitch

B-Scan/UBM or Combo Footswitch

Chapter 2
Set-up and Maintenance

1. Setup

A. INSTALLATION

a. Place OTI-Scan and computer on a flat surface. Position the system to ensure that the operator will be comfortable during use

b. Before connecting consoles, ensure that software is properly installed. See OTI-Scan 3000 Software Installation Instructions.

c. Connect power supply to OTI-Scan and AC power. Connect computer to AC power

d. Connect Firewire cable to OTI-Scan and computer

e. Connect all probes

f. Switch on the OTI-Scan, then switch on the computer

g. Install and connect printer in accordance with manufacturer's instructions

B. VENTILATION

Like other electronic equipment, the OTI-Scan 3000 produces heat, which must be exhausted for correct system operation. Keep the unit away from walls to allow air circulation and never cover the unit even partially (with protective cover, files etc.) during use. It is particularly easy for laptop computers to overheat when used in confined spaces.

C. PRINTERS

The OTI Scan 3000 is designed to use standard printers (the printer must be Windows compatible). Print speed and quality will depend on the printer chosen. An inkjet printer will provide better image quality; laser printers are faster and more economical to operate. In general, the printer is not supplied. OPTOS can only offer limited assistance with the installation of printers.

Printer Installation

All printers should be installed according to the directions in the user's manual supplied with the printer, using the correct Windows drivers. Drivers and driver installers for a limited selection of printers may be pre-installed on the OTI Scan 3000.

2. Maintenance

Cleaning

Clean the case with a damp cloth. Use appropriate products to clean the computer, keyboard and monitor. Cables may be cleaned with a soft cloth and alcohol.

The probe holder should be washed with warm water and a mild detergent to prevent build-up of gel.

Probe handle and transducer:

The user must use the following procedures to clean the transducer and probe end daily.

Material:

Distilled water

Soft facial tissue

Photographic lens cleaning paper

Procedure:

Keep the transducer and probe connected, rinse the transducer and probe end thoroughly with distilled water.

Wet a piece of soft facial tissue; absorb water remaining on the transducer surface and probe end by without rubbing

Inspect carefully for salt build up on surfaces

If there are any salt crystals, wet lens cleaning paper with distilled water, and then very lightly wipe clean any salt build up on the transducer surface.

If there is salt built up around the connector, remove the transducer from the probe, and use lens cleaning paper remove the build up. Then reconnect the transducer and hand tighten.

Rinse the transducer and probe top end with distilled water

Leave the transducer and probe to air dry.

Note:

This maintenance procedure is not intended for disinfection of the transducer and probe. Disinfection must still be performed between patient exams, following the procedures outlined below. Daily cleaning of the transducer and probe must be done at the end of the working day, when no further exams are expected. If an emergency examination must be performed outside normal working hours, the probe and transducer must be disinfected and completely cleaned immediately afterwards.

Disinfection

The probe must be cleaned and disinfected between patients to prevent the transmission of infections. It is the user's responsibility to ensure that the relevant standards are maintained and that the products and procedures are effective and appropriate for ophthalmic applications. The following information is provided for the guidance of users, and specific products are mentioned for illustration only; OPTOS does not endorse the use of these or any other product. Products must be used in accordance with the manufacturer's instructions.

FOR U.S.A. ONLY

How to prevent patient-to-patient transfer of infection

The probe must be cleaned between two patients to prevent patient-to-patient transfer of infection.

The probe may be cleaned using Cidex liquid disinfectant, usually found in hospitals. Other FDA-cleared disinfectants may also be used.

Probes and cables can be immersed up to the connector.
Do not immerse the connectors.
Do not autoclave the probe or the cable.
After cleaning, rinse the end of the probe thoroughly with clean water to remove all traces of the liquid used.
Follow the instructions on the label of the disinfectants.
The surfaces should then be dried with a lint-free cloth.

FOR EUROPE

PRECAUTIONS TO BE TAKEN TO AVOID THE SPREAD OF INFECTIOUS DISEASES, PARTICULARLY CREUTZFELD-JACOB DISEASE, WHEN USING OPHTHALMIC ULTRASOUND PROBES.

PREAMBLE

– The standard protocol must be used to ensure satisfactory decontamination – predisinfection and disinfection of the probe after use.
– The risky patient protocol must be used to ensure satisfactory decontamination – predisinfection and disinfection of the probe after use on a patient where there is a risk of transmission of Creutzfeld-Jacob disease.

OPERATOR'S CLOTHING

– Single use overall.
– Disposable gloves, sterile for disinfection.
– Glasses and anti-projection masks.

EQUIPMENT

– Soft silk brush (surgical nail brush).
– 3 x 500 ml stainless steel (or plastic), autoclavable-soaking trays.
– Single use hand cloths (e.g. Kimwipes ®).
– Demineralized or distilled water.

PRODUCTS

– Cleaning/pre-disinfectant: Aniosyme ® P.L.A. (Company: ANIOS),
  or pre-disinfectant: Alkazyme ® alcalin (Company: ALKAPHARM).
  The products must be diluted at 0.5% with warm water (25°C - 30°C) from the tap or distilled water. The contents of the tray must be changed every day.
– Disinfectant type Alkacide ® (Company ALKAPHARM).
  The product must be diluted at 5% with distilled water.
  The solution must be changed every day.
– 6 Chlorometric degree solution of sodium hypochloride at 20°C.
  The contents of the tray must be changed after each use.
– Demineralized or distilled water.

REMINDERS

– Disconnect the probes from the machines.
  Machines MUST BE TURNED OFF before disconnecting probes.

Warning: Avoid splashing liquids onto probe connectors (end of the cable which is connected to the machine).

PREPARATION OF DECONTAMINATION AGENTS

A) DECONTAMINATION • PREDISINFECTION AGENTS

- Proteolytic enzyme based agents (2 possibilities)

1 - 0.5% ALKAZYME solution in water (20g packet).

Prepare according to manufacturers instructions. The Alkazyme solution can be used for 8 days if kept in a sealed flask. The solution can also be made up in a 4 L recipient using distilled water and fill up the soaking tray from there.

OR:

2 - 0.5% ANIOZYME solution in water (25g packet).

Prepare according to manufacturers' instructions. The Aniozyme solution lasts 1 day in a sealed flask.

B) DISINFECTION AGENT

1 - 5% ALKACIDE solution in water

Prepare according to manufacturers' instructions

The Alkacide solution will keep for 8 days in a sealed flask.
Fill soaking tray (500ml) when disinfection is necessary.

C) RENEWING CONTENTS OF SOAKING TRAYS

For frequent use, the contents of the trays should be replaced at the beginning of the morning and at the beginning of the afternoon. Wait 10 minutes after the last decontamination before emptying out the Alkazyme or Aniozyme solutions.

Standard Protocol

1. Immerse the probe and the cable (except for the connector) in a solution of either ALKAZYME or ANIOZYME for 5 to 15 minutes depending on the perceived level of risk.

2. Clean the probe and the cable in the chosen solution for 1 minute using the brush.

3. Rinse the probe and the cable in de-mineralized or distilled water. Do not wet the connectors.

4. Dip the probe and the cable in the Alkacide solution for 5 to 20 minutes depending on the estimated level of risk. Do not wet the connectors.

5. Rinse the probe and cable with de-mineralized or distilled water. Keep the connectors dry.

6. Dry with a sterile compress or a single use dry wipe if the rinsing water was sterile.

7. The probe is ready for use.

Protocol for High-Risk Patients:

Reminder:

Disconnect the probes from the machines. Machines must be turned off first. Avoid any contact between liquids and the electrical connectors at the ends of the probes.

Decontamination – Pre-disinfection: Immerse the probe and the cable (except for the connector) in a solution of either ALKAZYME or ANIOZYME for 5 to 15 minutes depending on the perceived level of risk.
Clean the probe and the cable in the chosen solution for 1 minute using the brush. Do not splash the connectors
Rinse the probe and the cable in de-mineralized or distilled water. Do not wet the connectors.
Immerse the probe and the cable (except for the connector) in a 6 chlorometric degree solution of sodium hypochloride for 60 min at 20°C ensuring the connectors are kept dry.
Rinse the probe and cable with de-mineralized or distilled water.
Immerse the probe and the cable (except for the connector) in the ALKACIDE solution for 15 minutes
Rinse the end of the probe with de-mineralized or distilled water. Keep the connectors dry.
Dry with a sterile compress or a single use dry wipe if the rinsing water was sterile.

Reminder:

The contents of the trays should be allowed to stand 10 minutes after disinfection is complete before replacement.

Chapter 3
Operation: Basic Functions

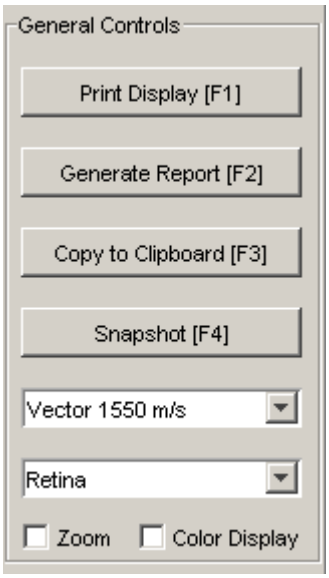
The operation of the OTI Scan 3000 revolves around the computer and monitor. All functions are controlled through the screen and the computer and all results are displayed on the monitor screen. The system includes a holder and calibration block for the probes.

At the start of an examination, the operator sees the Patient List, which allows selection of examination mode or access to patient files. The scan being taken appears on the acquisition screen. The scan can be frozen or unfrozen on this screen by using the mouse or foot switch. "Buttons" on the screen permit storage of the scan, freezing, printing, and measurements. Moving markers to various anatomical points makes measurements. The distances between these markers are then indicated on the screen. In biometry, the measurement may also be taken automatically, by choosing automatic freeze on the Acquisition screen.

When a function is not available, the corresponding control is greyed out, and doesn't respond.

This panel, in the upper right corner of each screen, shows the current patient, the date and time, and the current assignment of the footswitch pedals. In this case, pressing the left pedal saves the current scan and pressing the right pedal will start a new scan – clicking on them will have the same effect as pressing the pedal does.

The General Controls panel contains functions that are common to multiple scanning and viewing modules:



Print Screen sends the current scan to the printer, providing quick output where a full report is not desired.

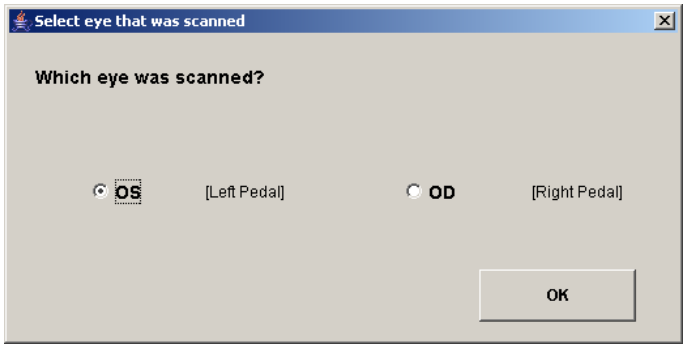
Generate Report copies the current view to the Report module, where observations, comments and diagnostic evaluation can be added. Additional images can be inserted from the clipboard when it is enabled.

Copy to Clipboard and **Snapshot** options are available

The **measurement mode** and **scan mode** lists will offer the options that are available in the current scanning module.

Zoom zooms the image 4x

Color Display generates a false-colour image.



Many functions require information about the eye that was scanned. If this has not been entered, starting these operations will open a dialog requesting that the eye be specified. This can be done by clicking on the button or pressing the corresponding footswitch pedal.

Footswitches

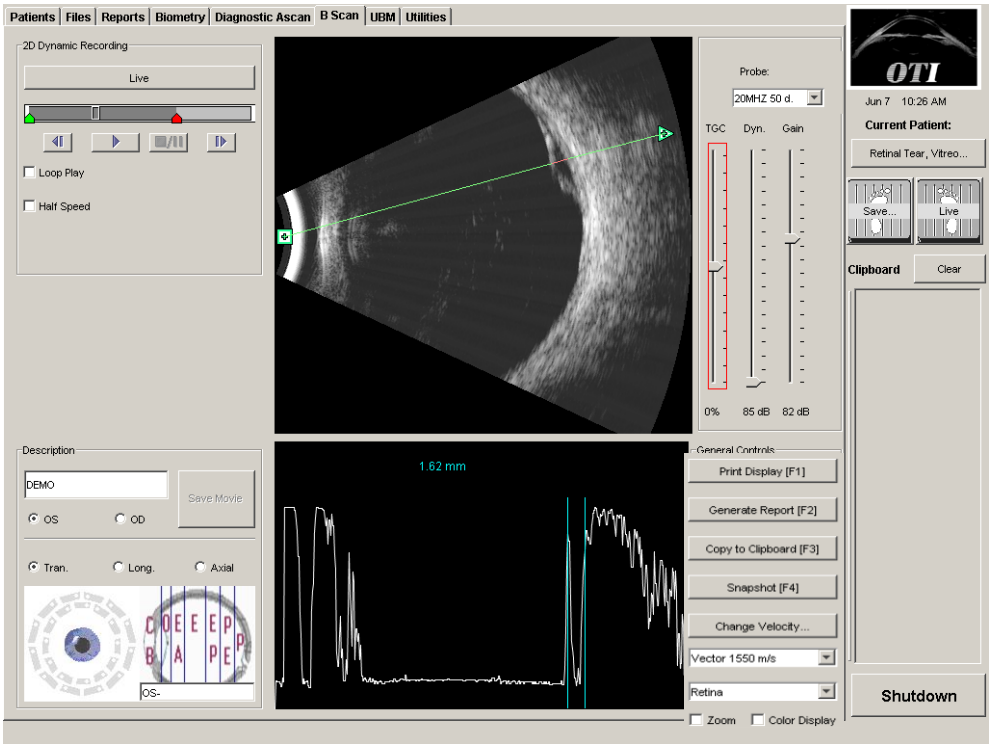
A-Scan Footswitch

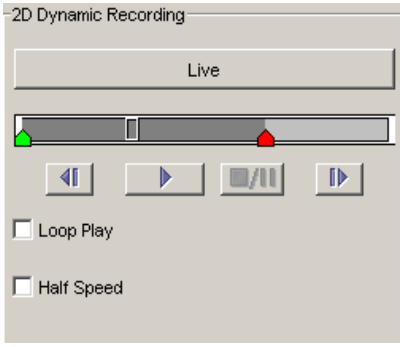
B-Scan and UBM Footswitch

For all B and UBM systems, the USB footswitch shown to the left is supplied. The left and right pedals have the functions displayed on the footswitch icon. The centre pedal acts like clicking “OK” in a dialogue box, or it moves the focus between any of the 4 slider controls that are visible: Gain, Contrast, TGC and the Frame Counter (See Page 38)

1. B Scan

Before starting a scan, transducers must be cleaned and disinfected. (See Pages 26-31)





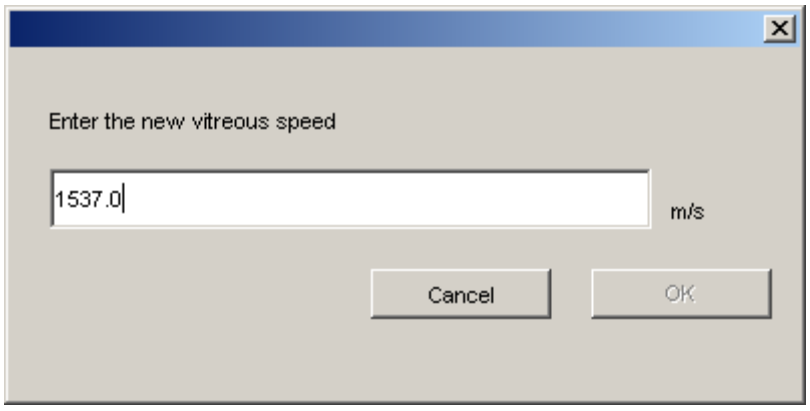
The B scan module shows the image with a simultaneous A scan profile. Start recording by clicking **Live**, or pressing the right footswitch; end by pressing the right footswitch or pressing Stop. The recording can be played back using the controls below the Frame Counter bar. Particular frames are selected using the Left and Right buttons or dragging the cursor along the bar. A specific section of the recording can be selected for playback by placing the green Start and red Stop markers inside the Frame bar. These are the frames that will be saved to the patient's folder if this option is available. The slider on the bar indicates the position of the current frame in the recording, and can be used to move through the sequence by clicking and dragging.

The A-Scan Vector/Profile cursor is the green and red line running through the B Scan image. The Vector/Profile displays the intensity of the echoes in the image as a classic A-Scan curve. Clicking and dragging its left end changes the vertical position of the cursor. Clicking and dragging the right end changes the angle. The profile is displayed in the window below the image; linear measurements are made by dragging the vertical cursors to the appropriate points on the profile. The red section of the Profile cursor shows the interval being measured.

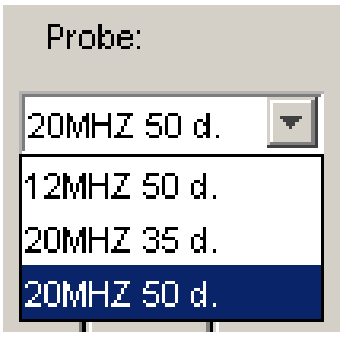
Change Velocity

To ensure accurate length measurements, the tissue velocity must be set to an appropriate value for the eye being examined. Where there has been a vitrectomy with silicone oil replacement, or the measurement range includes other structures where the velocity differs from the normal 1532m/s, the correct value can be entered by clicking **Change Velocity**, and entering the new value in the dialog box. In complex cases, it may be necessary to make the measurement in segments, entering a value for each segment. In this situation, the Clipboard can be used to store each segment for inclusion in the report.

Caution: The velocity will be set at the new value until it is changed again or the program terminates.



Select Probe Frequency



Transducer frequency and sweep angle are selected from the **Probe** list.

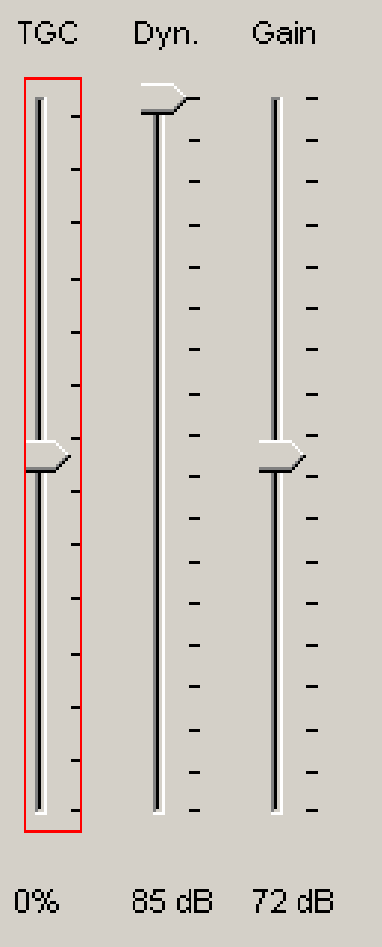
The probe may be applied directly to the eye or used with an immersion cup. To start a scan, place gel on the probe and place the probe on the eye (or place the cup on the eye and fill with sterile saline), and click on to start the transducer moving. Place the probe in the cup and move it towards the eye until the cornea appears at the bottom of the image.

Caution! Applying excessive pressure to the probe will cause discomfort for the patient and distort the eye.

Select Scanning Zone/Depth

Orbit mode: The normal scan depth is 37mm from the face of the probe. Selecting Orbit improves visualization of deep structures; the field of view is then 8-45mm

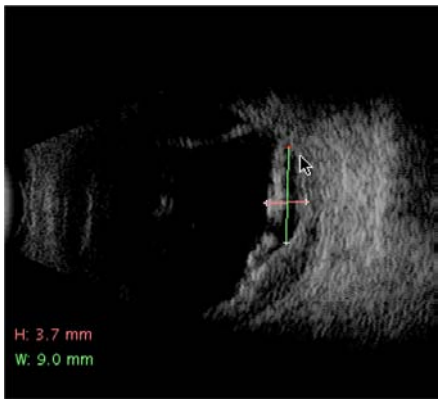
Image Adjustments

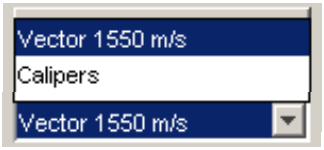


These three sliders control the TGC, brightness and contrast of the image. When the image is live, they are set either by clicking and dragging the slider with the mouse, or turning the control knob on the console. The highlighted slider is currently being controlled by the knob; it may be changed either by clicking with the mouse, or by pressing & releasing the knob. These controls must be adjusted to obtain the best image while scanning; while they have the same visual effects on a frozen image, it is important to remember that they are acting on stored data. If the data is not captured when the image is made, the detail cannot be created later by adjusting these controls.

Time Gain Compensation (**TGC**) corrects the image for the natural attenuation of ultrasound in tissue. Less sound reaches deep tissues, and the echoes are correspondingly weaker. This is seen on the screen as a fainter echo, even when the tissue has, in fact, the same reflectivity as one nearer the probe. The TGC system compensates by applying more gain to late echoes than early ones – ideally, it matches the extra attenuation exactly. The degree of correction is set using the TGC slider. The system will automatically set the end of the first zone at the surface of the retina.

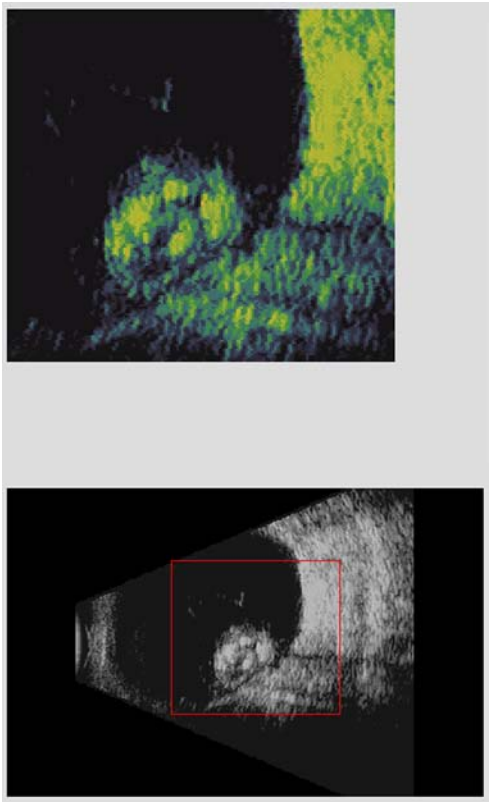
Measure B-Scan and UBM





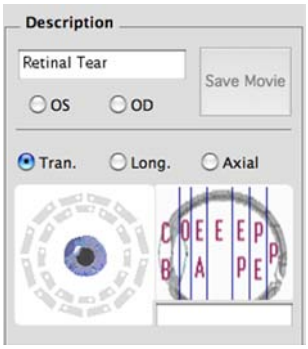
Selecting Calipers replaces the Vector cursor with a pair of linear cursors that allow linear measurements of the image. The cursors are placed by clicking on each end and dragging it to the required point. They will move independently, and there is no fixed relation between them. In this mode the Profile window is frozen.

Zoom and Color

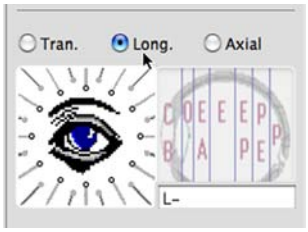


Clicking on Color creates a false-color rendering of the image. In B mode the color table is fixed.
Clicking on Zoom displays ¼ of the original image, magnified 2:1. The original image is shown in the lower part of the screen, with a box outlining the magnified area. Clicking and dragging inside the box will slide it over the image to select the area to be magnified.

Select Probe Position / Scan Orientation

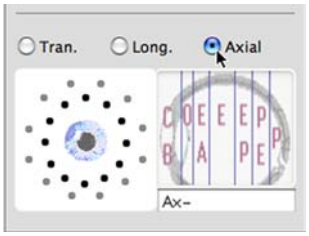


The Description field accepts a brief description of the pathology and identifies the eye that was scanned. This information will be attached to the file when **Save Movie** is clicked.



Position Marks

Indicate the probe position by selecting the view, then clicking on the correct location to show the probe orientation.

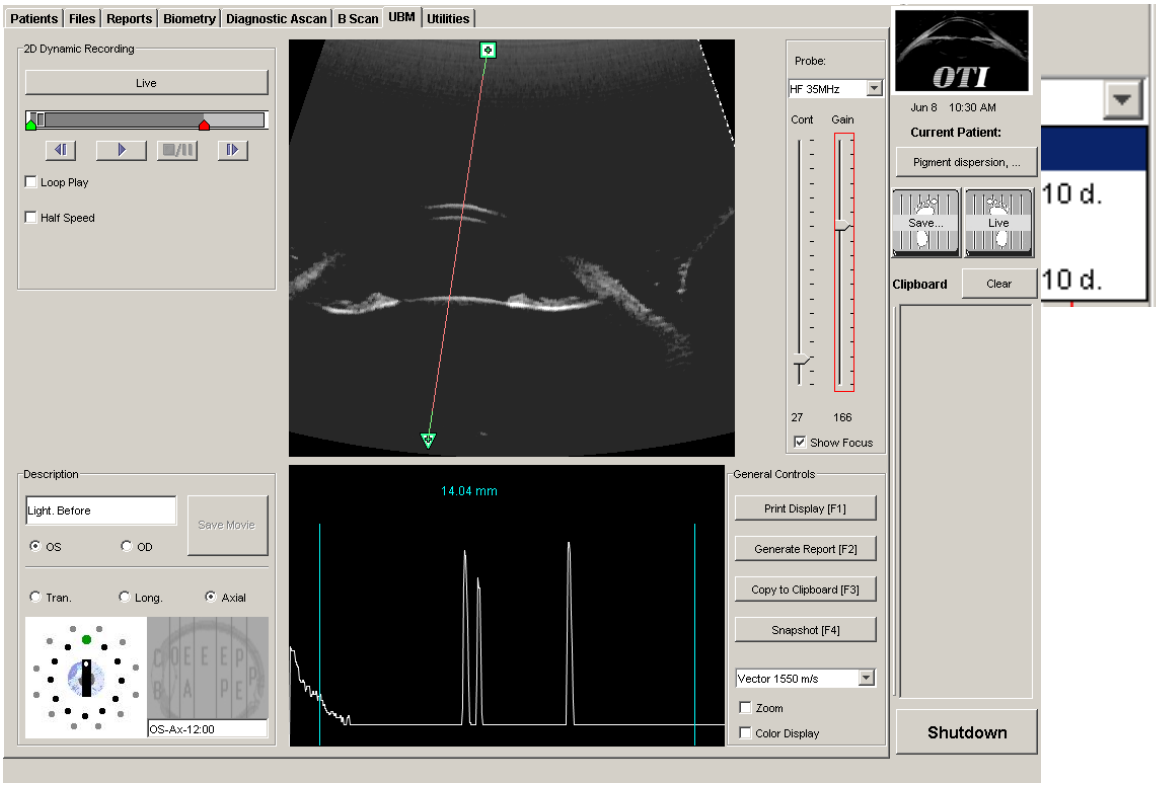


Markers are provided for transverse, longitudinal and axial views.

2. High-Frequency B Scan (UBM)

Before starting a scan, transducers must be cleaned and disinfected. (See Pages 26-31)

To enter the UBM module, click on the UBM tab. Aside from the probe selection and measurement functions, it is identical in operation to the B scan module.



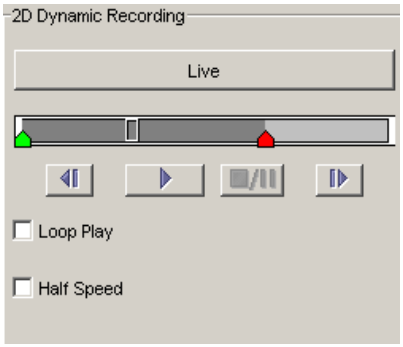
Scans can be made using the 35 or 50MHz transducer the system offers an image sector of 18° as well as the standard 34°, with twice the frame rate for the narrower sector. Click on Probe to select the correct value for the connected probe:

The probes **must** be used with an immersion cup.

DANGER!
CONTACT BETWEEN THE MOVING TRANSDUCER AND THE EYE CAN CAUSE SEVERE INJURY. THE USER MUST TAKE EVERY PRECAUTION TO PREVENT THE TRANSDUCER TOUCHING THE EYE.

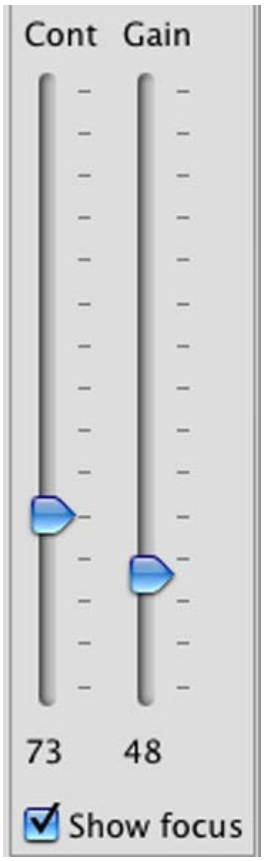
To start a scan, place the immersion cup on the eye and fill with sterile saline. Click on 

to start the transducer moving. Place the probe in the cup and move it towards the eye until the cornea appears at the bottom of the image. Proceed with the examination.



The UBM module shows the image with a simultaneous A scan profile. Start recording by clicking **Live**, or pressing the right footswitch; end by pressing the right footswitch or pressing Stop. The recording can be played back using the controls below the Frame Counter bar. Particular frames are selected using the Left and Right buttons or dragging the cursor along the bar. A specific section of the recording can be selected for playback by placing the green Start and red Stop markers inside the Frame bar. These are the frames that will be saved to the patient's folder if this option is available.

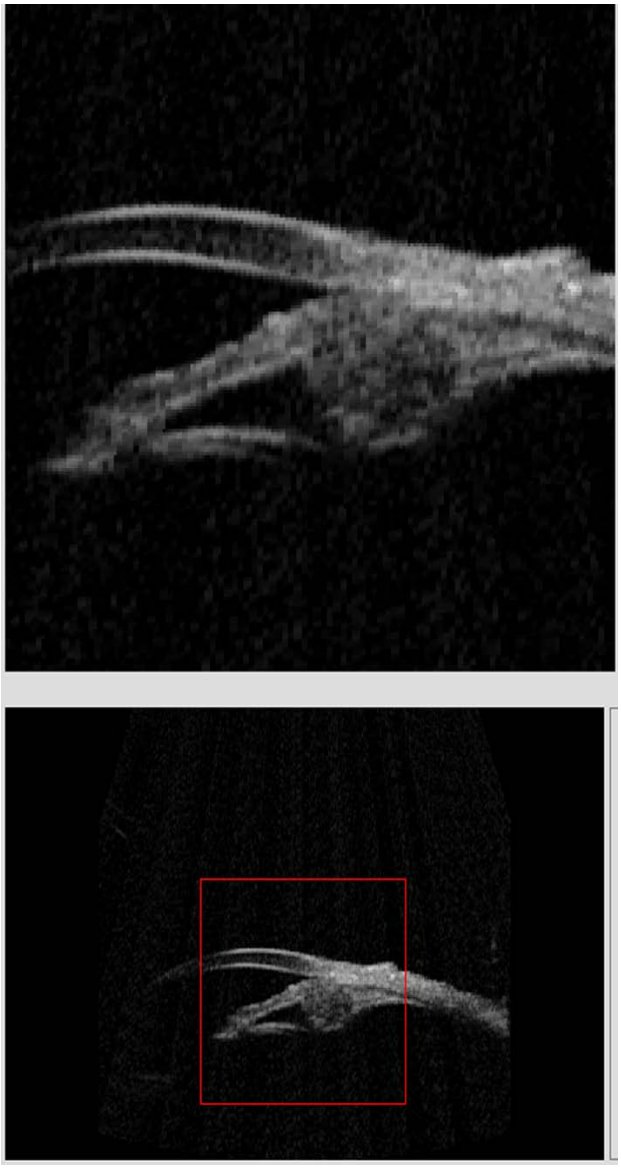
Image Adjustment



These sliders control the contrast and brightness of the image. They are set by clicking and dragging them with the mouse, or by pressing the knob on the console to select the slider, and rotating the knob. The highlighted slider is currently being controlled. These controls must be adjusted to obtain the best image while scanning; while they have the same visual effects on a frozen image, it is important to remember that they are acting on stored data. If the data is not captured when the image is made, the detail cannot be created later by adjusting these controls.

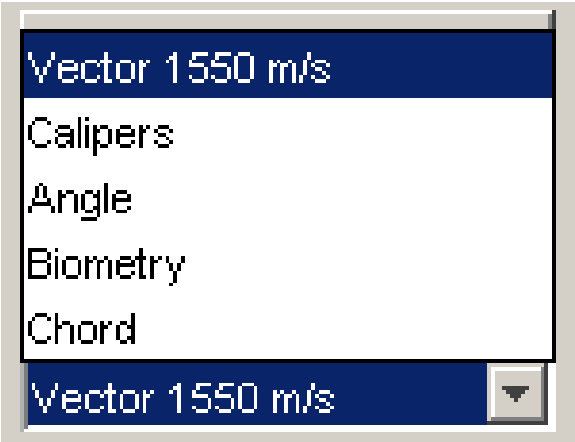
When **Show focus** is checked, lines are projected on the image indicating the focal zone of the transducer. This is the area where the image resolution is best. As far as possible, the structure of interest should be kept in this zone.

Zoom



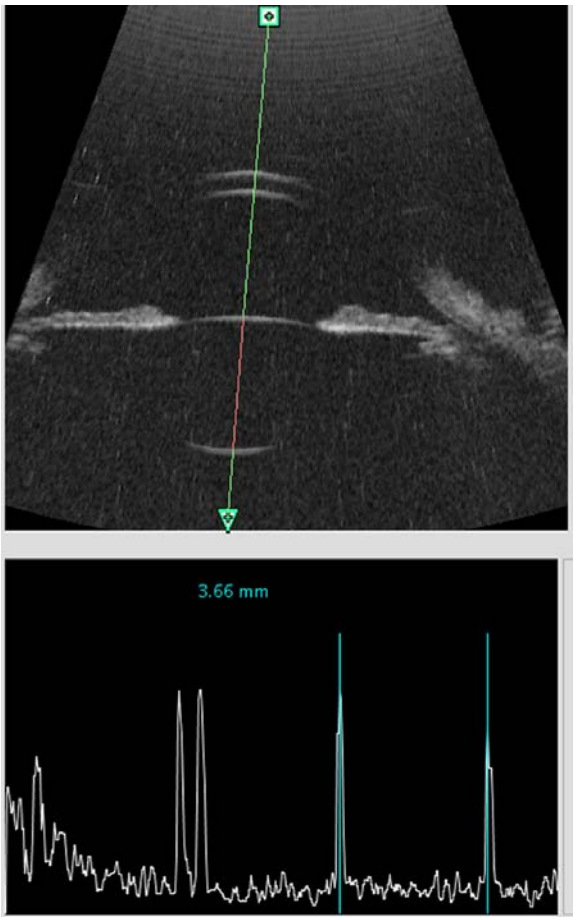
Clicking on Zoom displays ¼ of the original image, magnified 2:1. The original image is shown in the lower part of the screen, with a box outlining the magnified area. Clicking and dragging inside the box will slide it over the image to select the area to be magnified.

Measurements

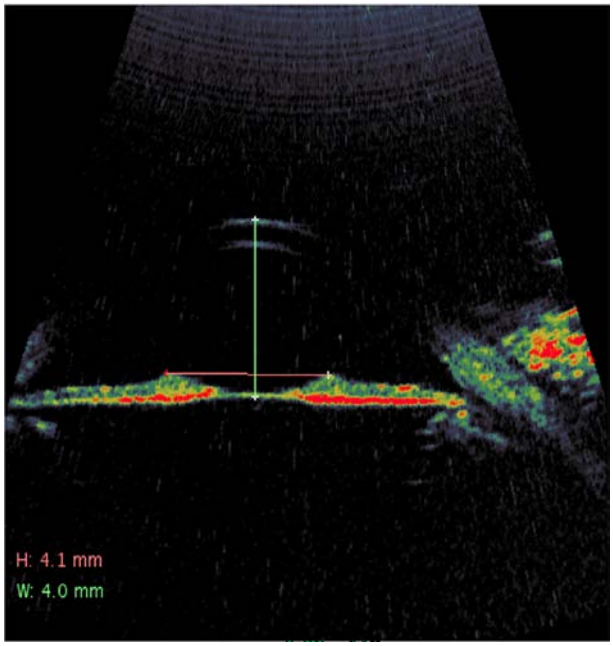


There are five measurement modes in the HF module: **Vector 1550** is a cross-vector measurement; **Calipers** gives two simultaneous linear measurements on the image; **Angle** measure, intended for measuring the anterior chamber angle, displays the angle defined by the cursors; **Biometry** measures distance along the optic axis, using the correct sound velocity for each segment; **Chord** measure is a special biometry mode intended for certain types of ocular implant.

Vector 1550



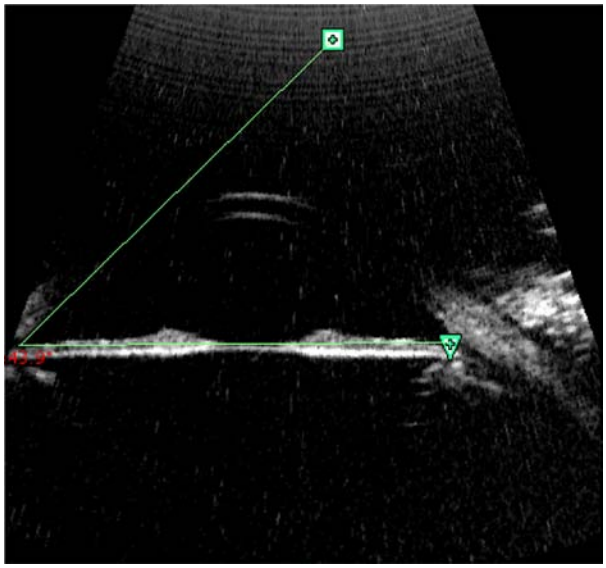
This is the default measurement mode. The cursor is the green and red line running through the image. Clicking and dragging its upper end changes the horizontal position of the cursor. Clicking and dragging the lower end changes the angle. The profile is displayed in the window below the image; linear measurements, assuming an average tissue velocity of 1550m/s, are made by dragging the vertical gates to the proper points on the profile. The red section of the Profile cursor covers the interval being measured.



Calipers

Clicking on H-W measure replaces the Profile cursor with a pair of linear cursors that allow linear measurements of the image using a tissue velocity of 1550m/s. The cursors are placed by clicking on each end and dragging it to the required point. They will move independently, and there is no fixed relation between them. The profile window is frozen in this mode.

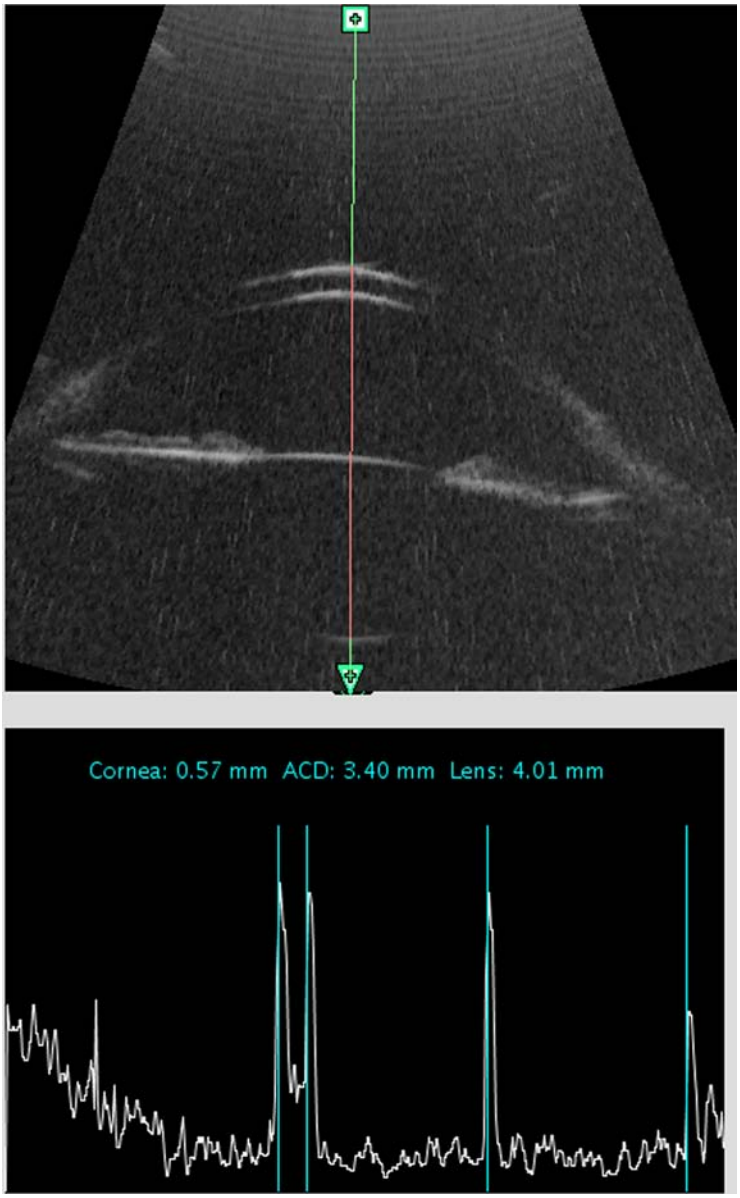
For this image Color Display has been checked, creating a false-color rendering of the image, using a fixed color table.



Angle Measure

To measure the angle between two surfaces, such as the anterior chamber angle shown above, check the Angle Measure box.

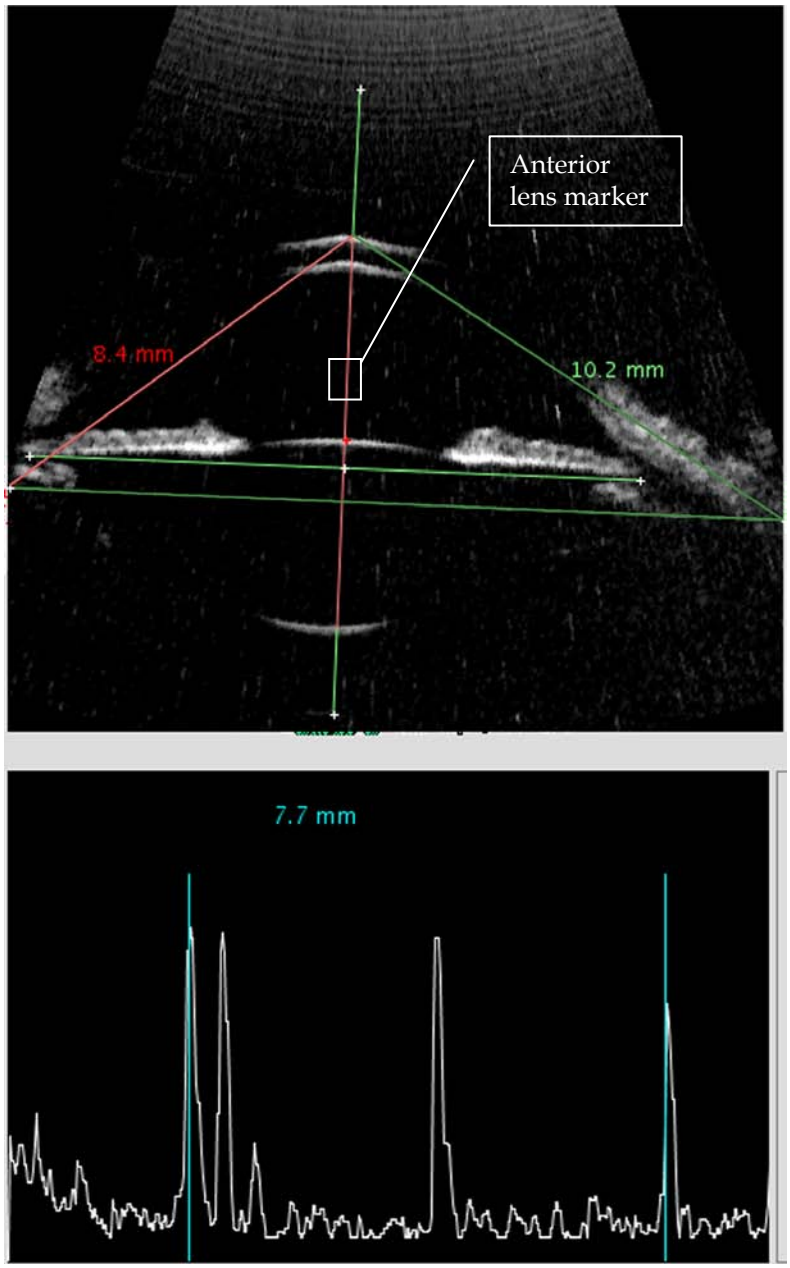
The apex of the angle and the end points of the sides are placed by clicking on them and dragging to the correct location. The sides can be any convenient length, but for the greatest accuracy they should be as long as possible. With the "lever" effect of a long arm, it is easier to make small changes in the included angle. The measurement is displayed below the apex.



Biometry

The Biometry module is intended to provide accurate distance measurements in the anterior segment, particularly along the optical axis. The components are recognized automatically, and the correct tissue velocities for each component are used: 1641m/s for the cornea and lens, and 1532m/s for the aqueous.

To make a measurement, use **Vector** mode to place the cursor on the axis, then click on the measurement mode list and select **Biometry.** The system will identify the anterior and posterior surfaces of the cornea and lens, and display the gates on the curve. The gates can be moved by clicking on them, and dragging them to the desired location.



Chord Measure

Chord Measure determines the chord length from the center of the corneal face to the sclera at a level marking 1/3 of the thickness of the lens.

Making a measurement requires an image that clearly shows the cornea, the anterior and posterior lens, and the sclera. Position the Profile cursor to trace the axis of the cornea and lens. This should give a profile similar to the one to the left. If any of the peaks are low, use another image.

Click on Chord Measure to display the cursors. Ensure that the marker is correctly positioned on the anterior surface of the lens. Drag the ends of the upper horizontal line to place it on the outer edges and parallel to the iris. The ends of the lower line are placed on the sclera. Verify that the upper and lower ends of the red vertical segment are on the anterior face of the cornea and the posterior face of the lens.

The chord lengths are displayed beside the chords.

ATTENTION:
The scans and readings displayed are presented for purposes of illustration only.
They are not intended to represent “correct” or “normal” readings.

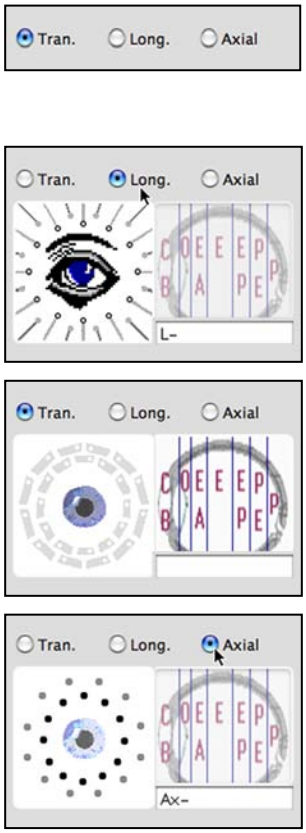
Description

The Description field accepts a brief description of the pathology and identifies the eye that was scanned. This information will be attached to the file when **Save Movie** is clicked

Scan Probe Orientation

Markers are provided for longitudinal, transverse and axial views.

Indicate the probe position by selecting the view, then clicking on the correct location to show the probe orientation.

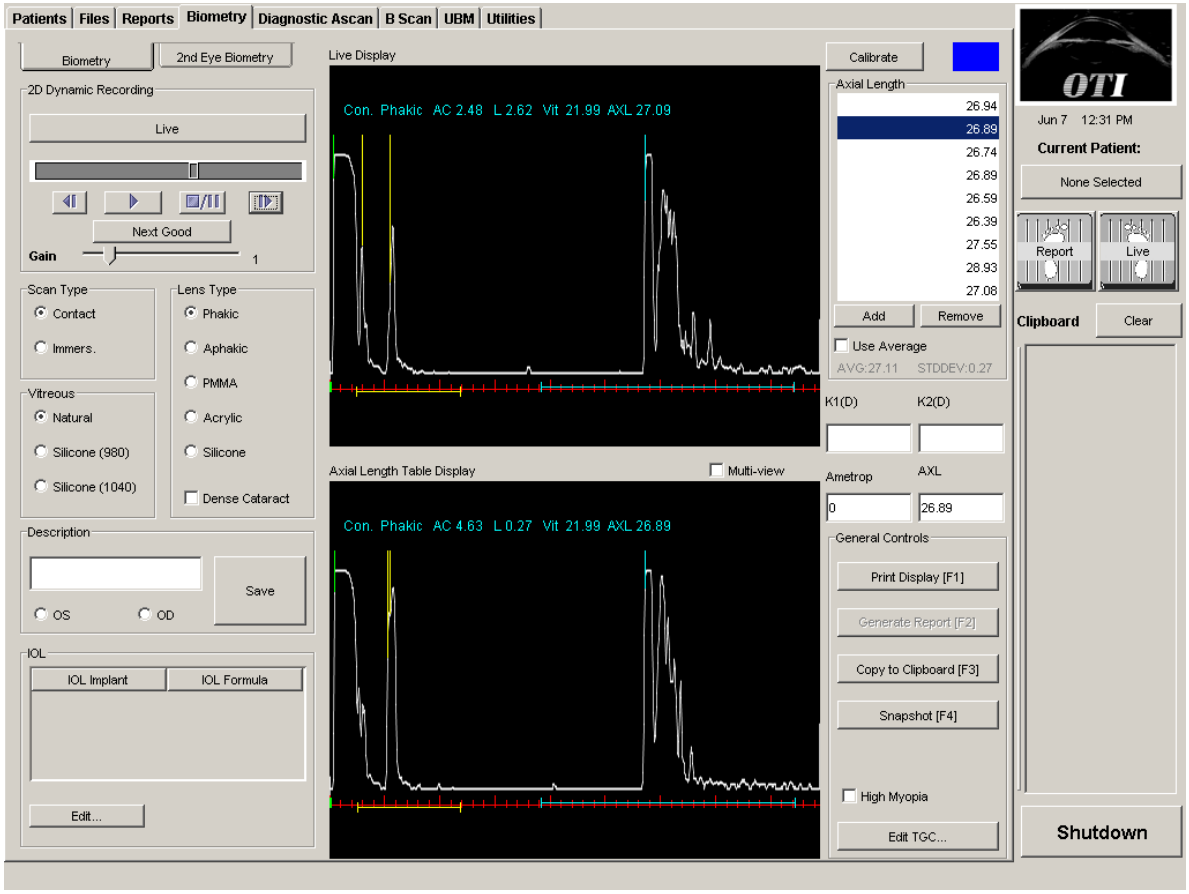


3. Biometry

Before starting a scan, transducers must be cleaned and disinfected. See Pages 26-31.

The system should be calibrated regularly (See Page 50).

NOTE: It is the operator's responsibility to place the probe properly, capture good scans and verify proper positioning of the gates.

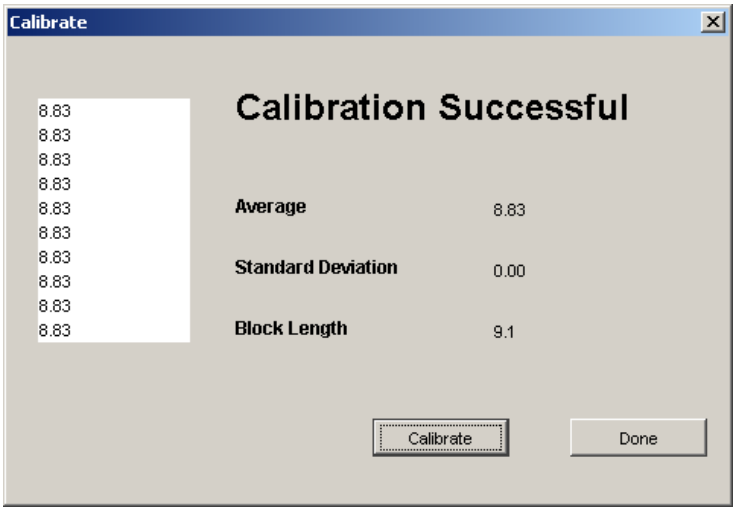


Calibration

The system should be calibrated at regular intervals.

Click 

to open the Calibration window:

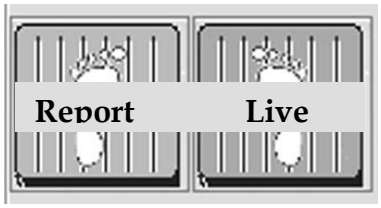


To calibrate the system, place the probe on the rear of the calibration block and click on Calibrate. The system will measure the block ten times, and compare the average length with the stored value. If the calibration succeeds, the window will display Calibrated and may be closed. If the calibration fails, contact OPTOS immediately. The blue rectangle beside the Calibrate button will turn green when the system is properly calibrated, or red if calibration fails.

Note: The test block will expand and contract with changes in ambient temperature. If the unit is operated outside the specified temperature range, calibration may fail.

A-Scan Examination

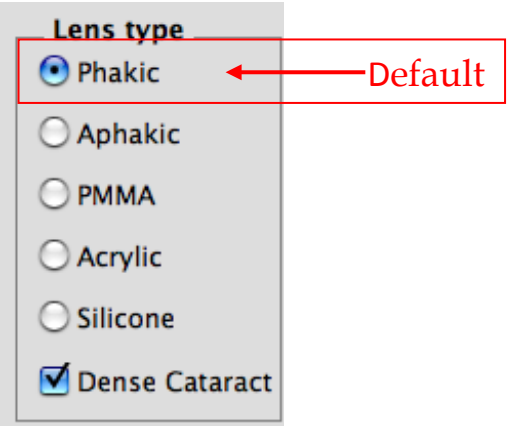
1. In A mode, pressing the right footswitch will Start/Stop a scan. Pressing the left pedal will create a Report.



2. Enter the Description and select the eye.

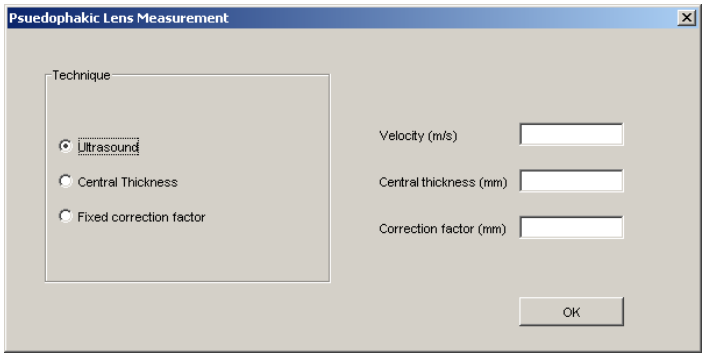
3. Click the corresponding tab to scan the other eye.

Select the lens/IOL type in the eye:



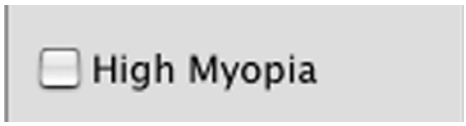
If there are problems obtaining adequate scans because of a very mature cataract, click on Dense Cataract.

NOTE: "Dense" mode offers a compromise between Log Amplification and Linear Amplification. It provides higher echoes from main structures in the eye, such as Anterior Lens (AL) and Posterior Lens (PL), as well as Retinal echoes, while lower echoes are suppressed. In Biometry, it offers easier acquisition and display for patients with dense cataract and/or a shallow anterior chamber. It also provides a better ratio between the AL and PL echoes and the retinal echo.

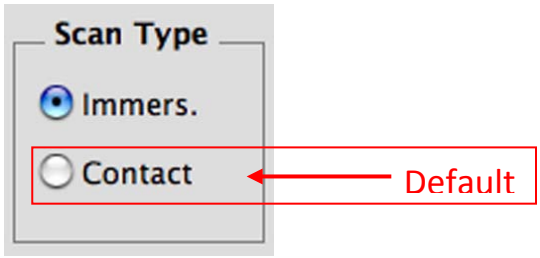


- Three options are offered for correcting for velocity variations in pseudo-phakic patients: Ultrasound, Central Thickness and correction factor.
- Ultrasound sets the tissue velocity for the lens to the correct value for the material and makes the measurement by identifying peaks as in a normal eye.
- To use Central Thickness, the user enters the thickness of the lens, as supplied by the manufacturer, in the dialog, and this value is used to calculate the axial length.
- If a fixed correction factor in diopters is entered, the correction will be applied to the calculated refraction.

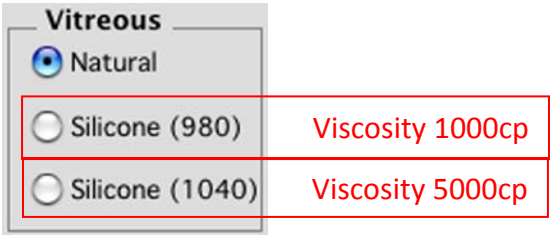
4. If the patient is a high myope, checking High Myopia will modify system presets and the scan evaluation to improve ease of capture:



5. Select the desired scan technique:



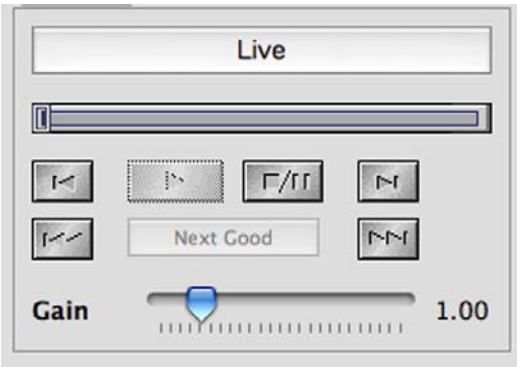
6. If the patient has had a total vitrectomy with silicone oil replacement, select the correct option in the **Vitreous** box. This sets sound velocity in the vitreous to the proper value for the oil used.



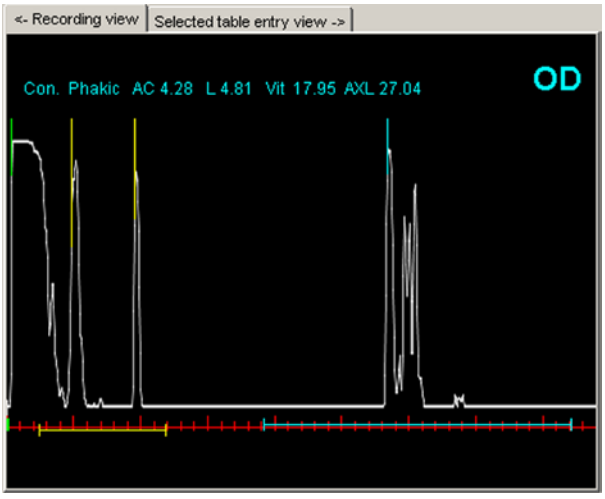
Caution: Choosing the wrong vitreous material will create serious errors in the axial length and calculation result.

7. Place the probe on the cornea, or in the immersion cup. When Live is clicked or the left footswitch pressed, the system will start recording scans, keeping the best 9 that have been recorded. The height of the scan is adjusted using the Gain slider, or with the knob on the console.

Caution! Applying excessive pressure to the probe will cause discomfort for the patient and distort the eye, resulting in incorrect measurements.



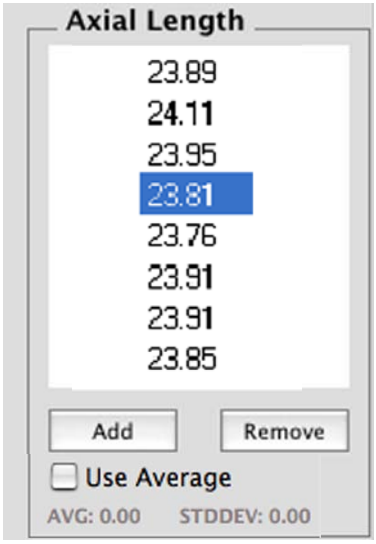
The system records the data during scanning. For manual evaluation and capture of scans, this recording can be played back using the standard controls: Start, Stop, Left, Right, Beginning and End. A frame can also be found by dragging the cursor on the Frame Bar. Next Capture will move to the next scan that the software identifies as acceptable.



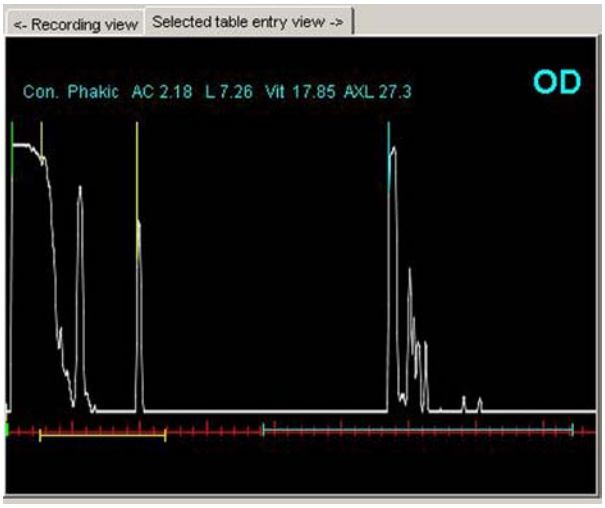
The axial length is displayed for each scan, with its three components: the anterior chamber, lens and vitreous.

The measurement cursors are positioned on the scan by clicking on them and dragging to the desired point. Click on Add (see next page) to add the scan to the list. The yellow and blue horizontal bars on the scale show the zones that are searched for the lens surfaces and retina. If the eye is unusually small or large, the zones can be changed by dragging the ends to the left or right.

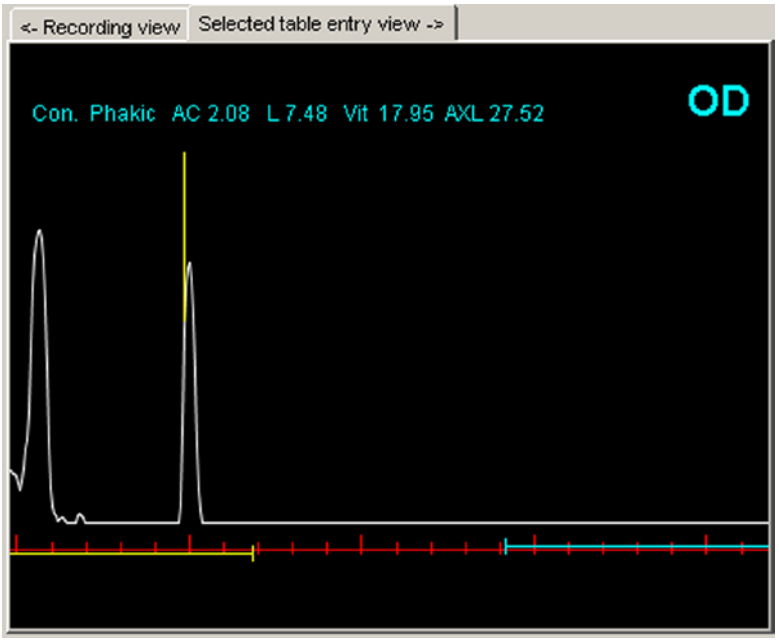
8. When the scans are acquired, they must be reviewed to ensure that they are of good quality. Clicking on the length in the Axial Length window selects the scan and displays it in the Axial Length Table Display window.



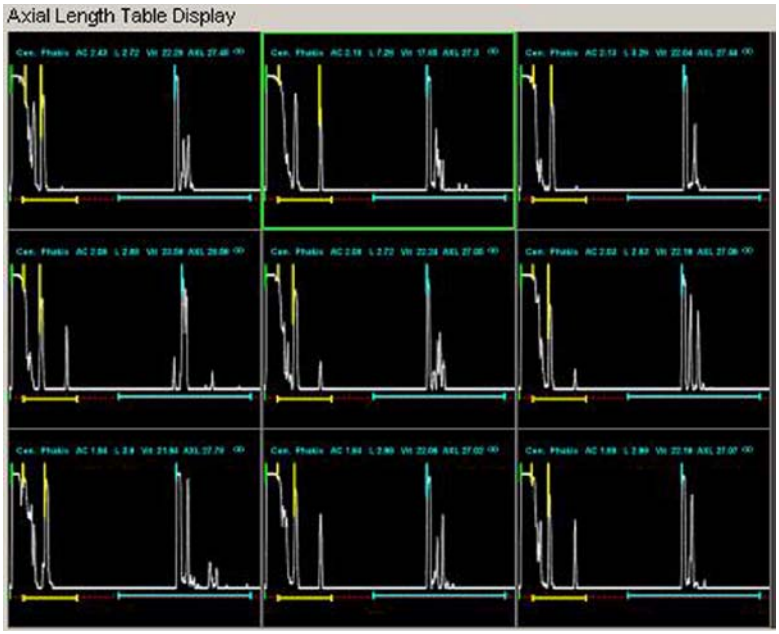
If Use Avg is checked, the average length will be used in the calculation. The average length and standard deviation are shown at the bottom of the panel. Clicking on Remove will delete the scan. Add includes the scan shown in the Recording View window. If more scans are needed, click on Live to start scanning and acquire more.



The measurement on a scan shown in this window can be edited, in the same way as in Recording View. The entry in the Axial Length table is updated automatically.

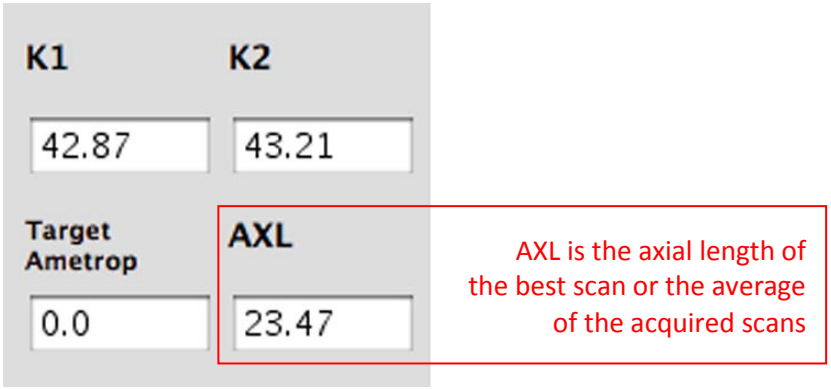


When a cursor is being placed, the scan is automatically zoomed to that part of the curve. This allows accurate placement of the cursor on the scan

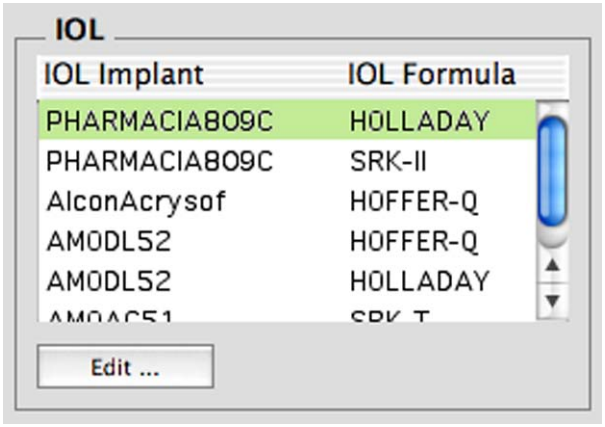


Miniature views of all the stored scans a displayed in a 3x3 table. Double-clicking on a scan will switch to "selected table entry view" with the selected scan displayed in that window.

9. Once a sufficient number of good scans have been acquired, the patient data must be entered. If the axial length is already known, it can be entered directly.



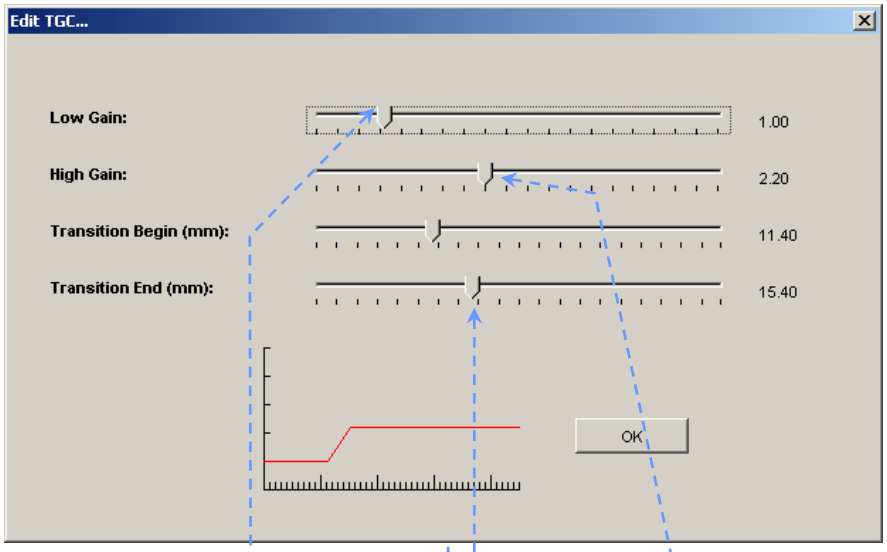
10. Select the correct IOL and formula for the patient.



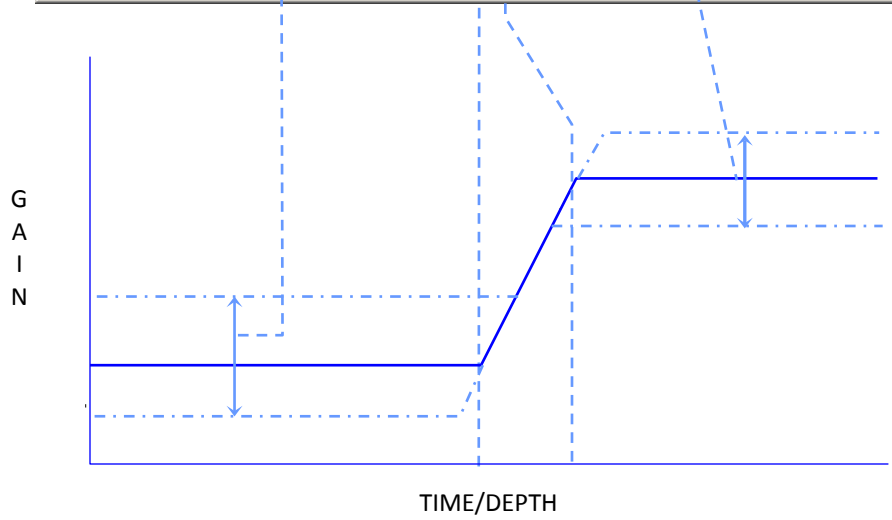
Clicking the Edit… button opens the Implants & Formulas window, where IOL constants and formula/IOL combinations are set up. (See Page 59)

11. Click on Generate Report to create and open the report for editing (see page 65). This button will not be active until all required information is entered. If both eyes have been scanned, data must be entered for both, even if a calculation is only required for the second eye.

This button opens the TGC editor:

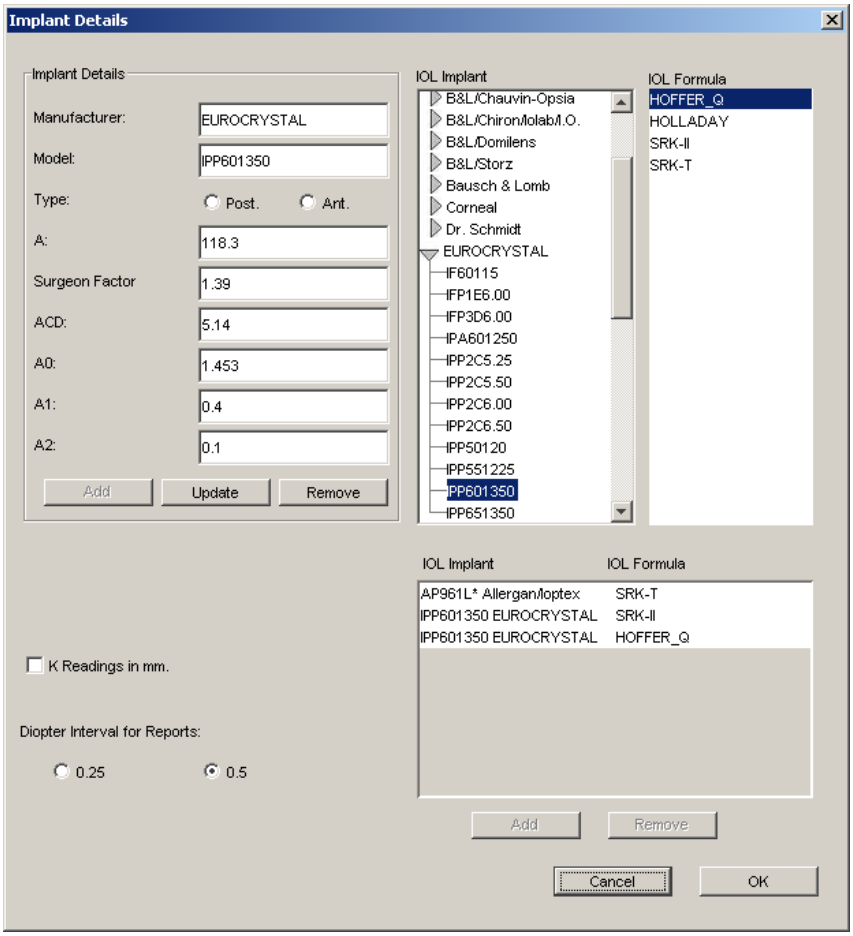


The values shown generally give the best results. As the sliders are moved, the red curve displays the effects of the changes



Time Gain Compensation (**TGC**) corrects the image for the natural attenuation of ultrasound in tissue. Less sound reaches deep tissues, and the echoes are correspondingly weaker. This is seen on the screen as a fainter echo, even when the tissue has, in fact, the same reflectivity as one nearer the probe. The TGC system compensates by applying more gain to late echoes than early ones – ideally, it matches the extra attenuation exactly. The gain levels for the anterior and posterior sections of the scan are set by adjusting the zone boundaries and the gain in each zone for the best view of each tissue. The initial and final gain values are set with Low Gain & High Gain; the position and width of the transition between them are set using Transition Begin & Transition End. The settings will be memorized. The sketch shows a typical TGC curve, with the sliders linked to the corresponding parts of the curve.

IOLs and Formulas



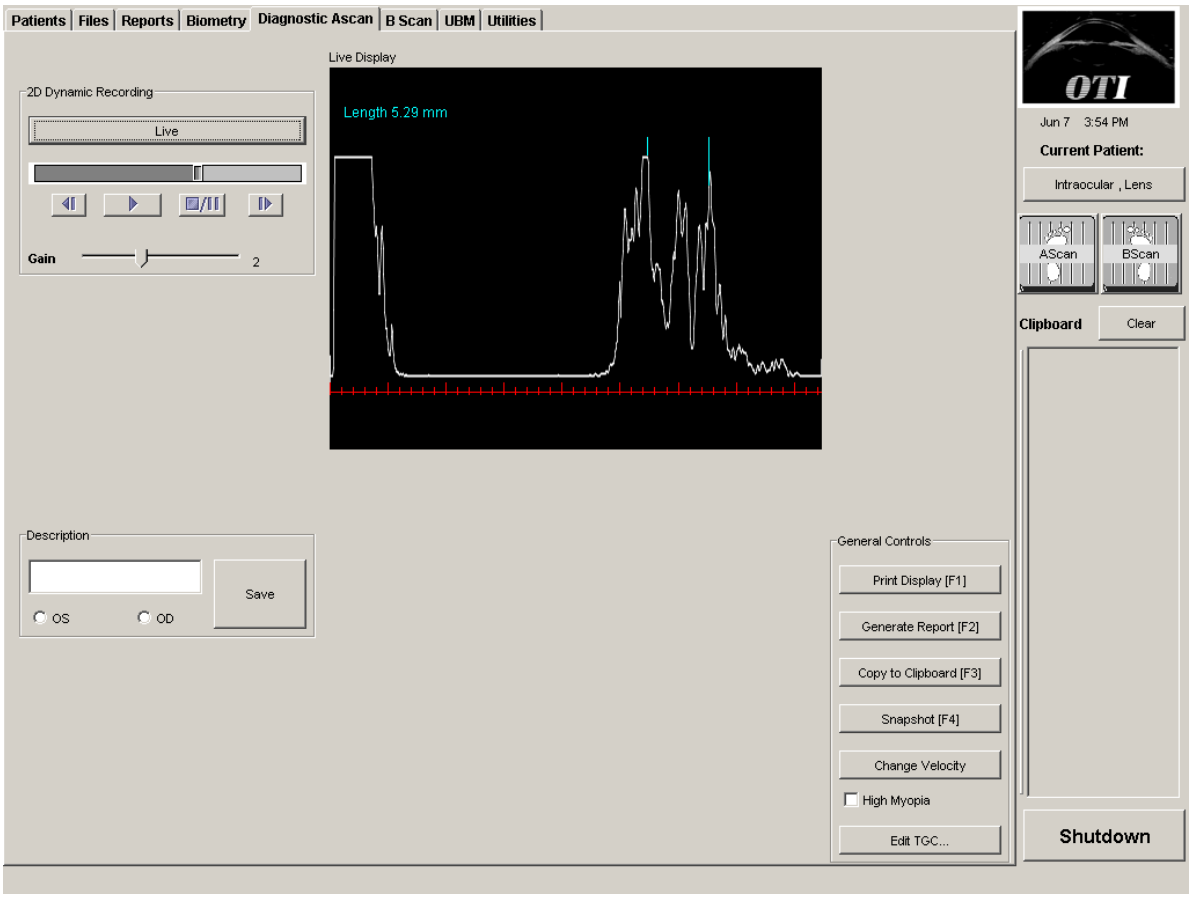
The software includes a list of available IOLs, with data provided by the manufacturers. To select an IOL, double-click on the manufacturer's name to open a list of IOL models, and highlight the selected lens.

To alter the default IOL selections, or add one not in the list, simply enter the manufacturer, model, type (Anterior or Posterior chamber), and the constants obtained from the manufacturer, then click on Update for an existing lens, or Add for a new lens. Remove deletes a selected IOL from the list.

Specific combinations of formulas and IOLs are created by selecting each from the individual lists, then clicking Add. A combination is deleted by selecting it from the Implant+Formula list, then clicking Remove.

4. Diagnostic A Scan

Click the Diagnostic A-Scan tab to enter A-Scan mode.



To record a scan, click on **Live** and placing the probe on the eye. Gain can be adjusted by turning the knob on the console, or moving the Gain cursor with the mouse or footswitch. The scan data is recorded in memory in a continuous loop, 10 seconds long. The moving cursor on the frame bar shows which frame is being recorded.

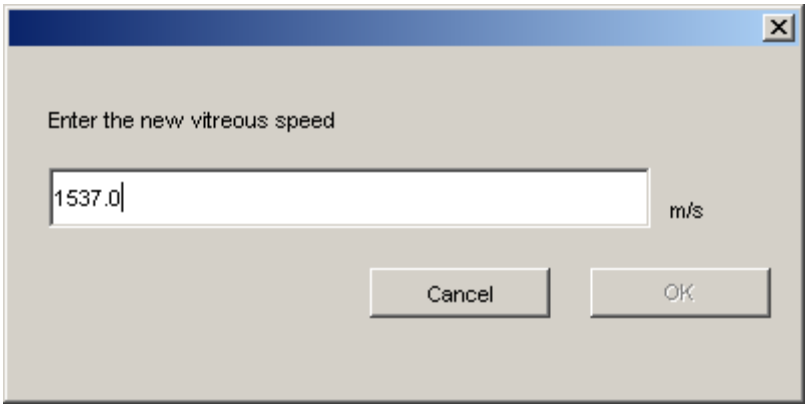
To freeze, press the left footswitch, or click the mouse. The recording can be played back using the controls below the Frame bar. Particular frames are selected using the Left and Right buttons or dragging the cursor along the bar. To make a measurement, click on each calliper and drag it to the required location.

The Description and General Controls are the same as in other modes: **Print** sends the displayed curve to the printer; **Generate** creates a report, and **Save** stores the data in the patient's folder.

Change Velocity

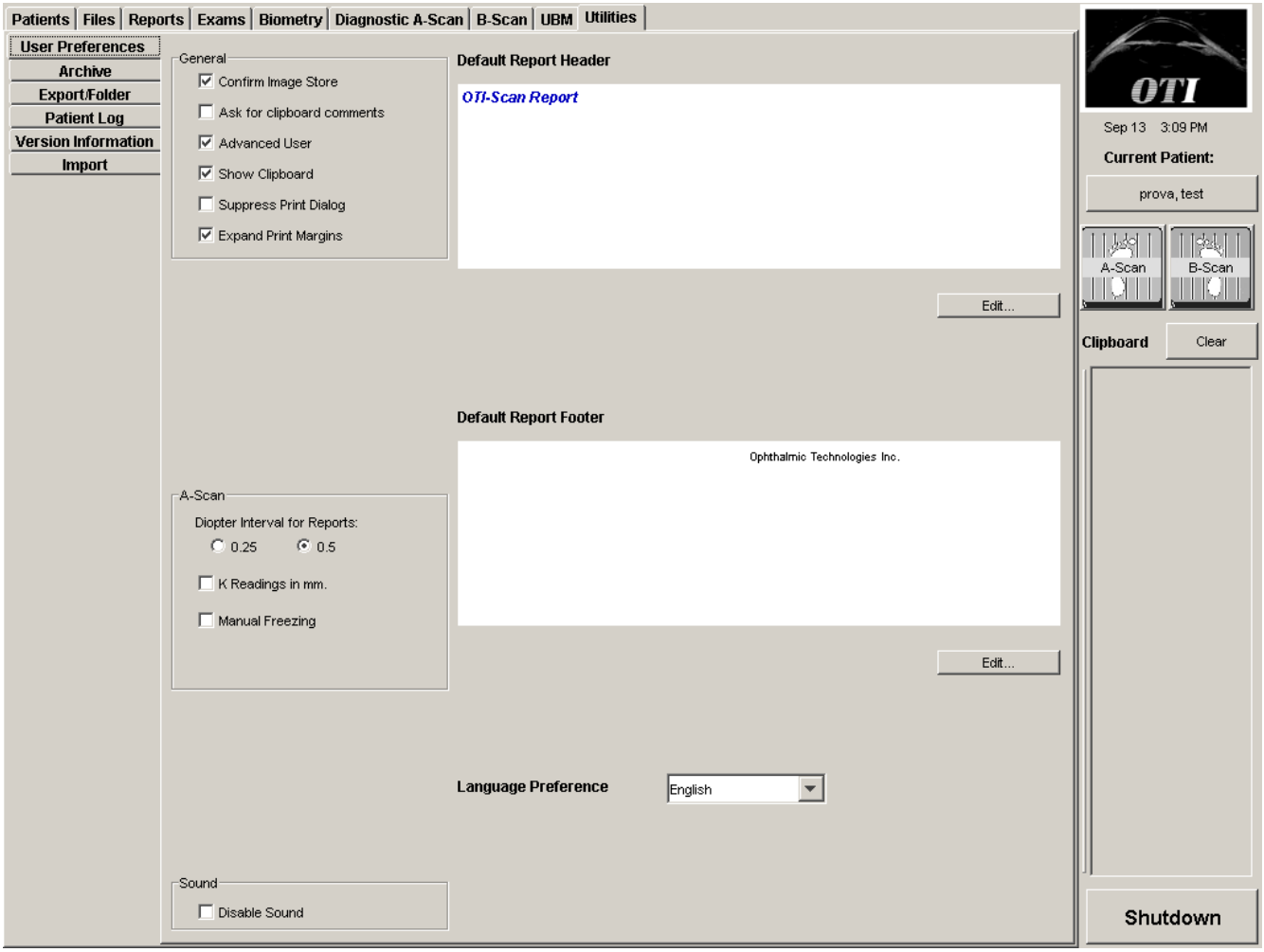
To ensure accurate length measurements, the tissue velocity must be set to an appropriate value for the eye being examined. Where there has been a vitrectomy with silicone oil replacement, or the measurement range includes other structures where the velocity differs from the normal 1532m/s, the correct value can be entered by clicking **Change Velocity**, and entering the new value in the dialog box. In complex cases, it may be necessary to make the measurement in segments, entering a value for each segment. In this situation, the Clipboard can be used to store each segment for inclusion in the report.

Caution: The velocity will be set at the new value until it is changed again or the program terminates.



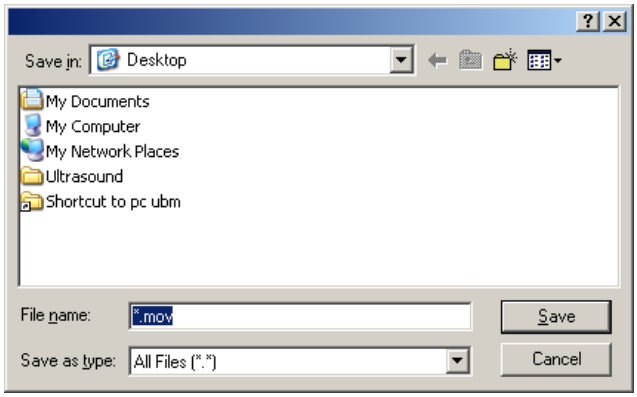
5. Utilities

The Utilities module contains a number of functions that are opened by clicking their tabs.



The Preferences page has controls for editing the header and footer of the report pages and controlling the display of various features in the software:

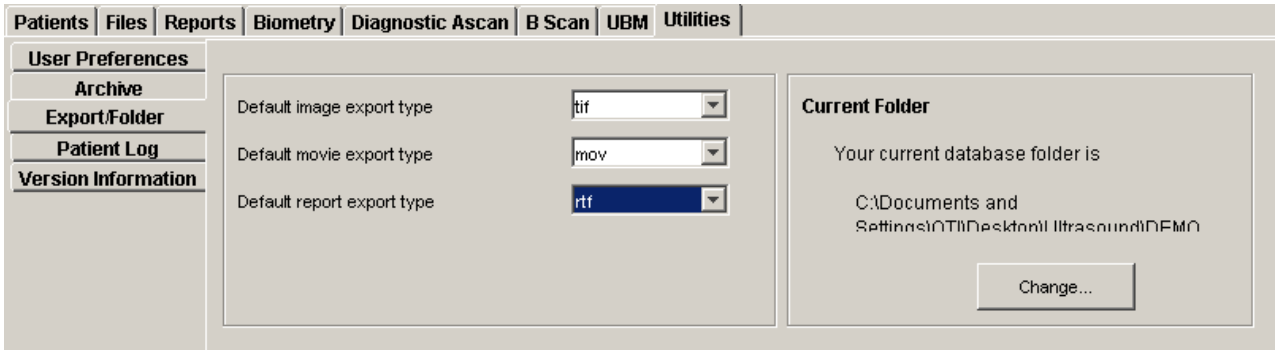
Selecting storage locations: Several functions offer the choice of selecting or changing the location where a file will be stored. They will all open the same Windows dialog boxes, which are used to scroll through the file system, open folders, and create new folders.

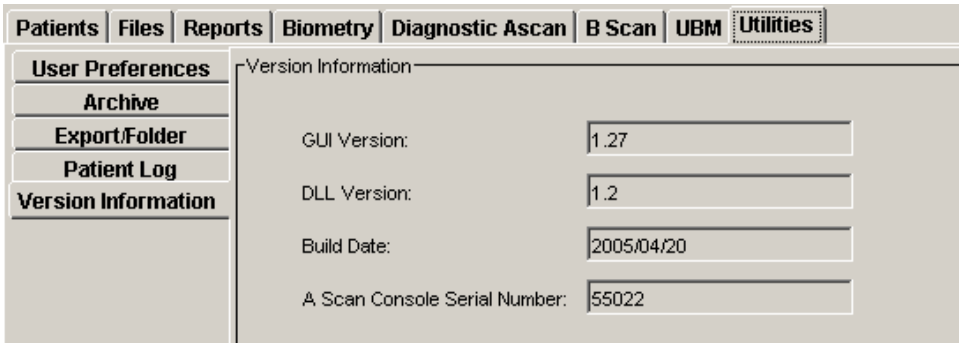


Folders are marked by a folder icon; data files are usually marked with the icon of the program that created them.

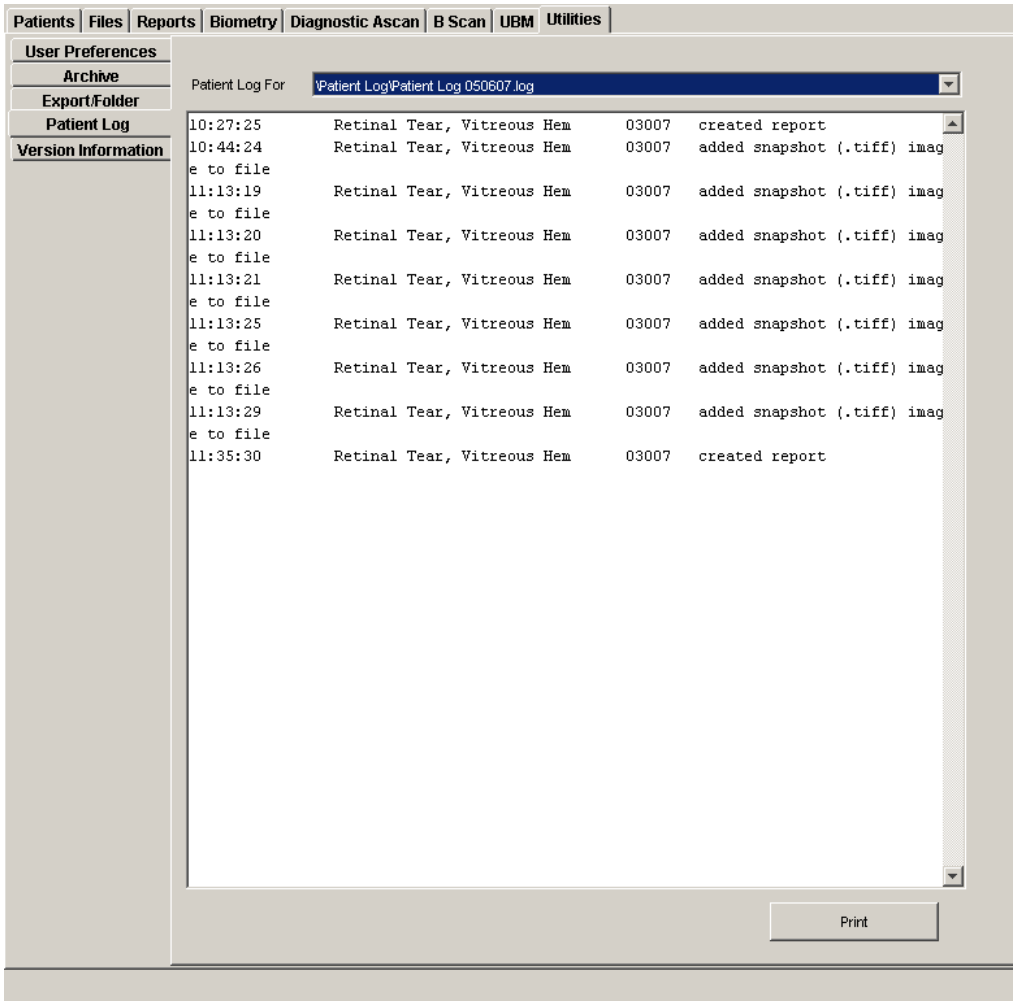
Click **Save** to save the file in the location listed in the ***Save In***: box.

The Export/Folders tab holds dialogs for changing the patient data folder and the file types used to export data.



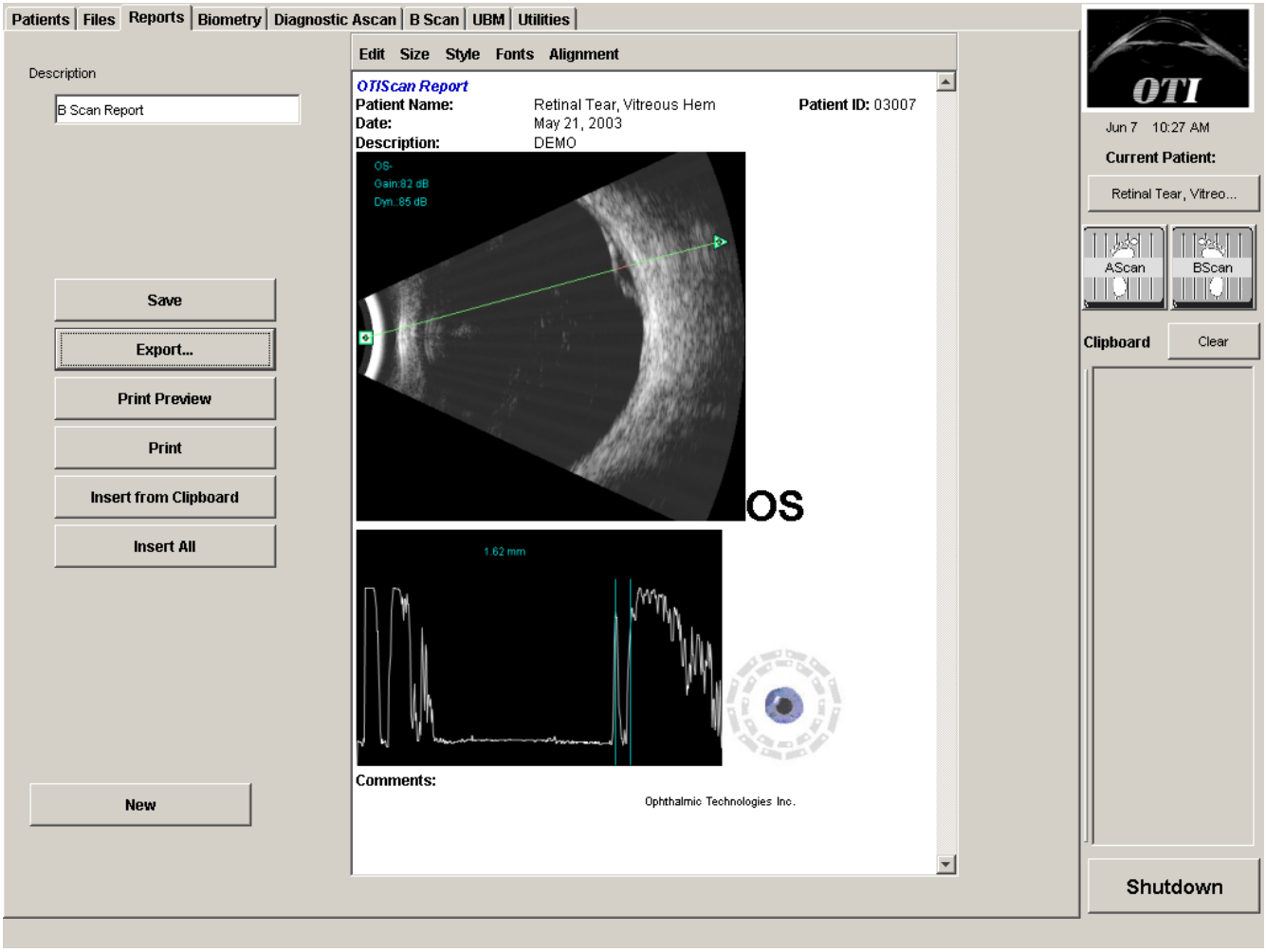


The Version Info tab gives the current software version, and provides the serial number of the console.



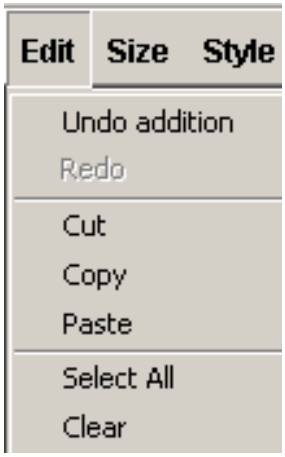
The Patient Log lists the examinations performed each day for the last week. If required, the list can be printed.

Chapter 4
Reports



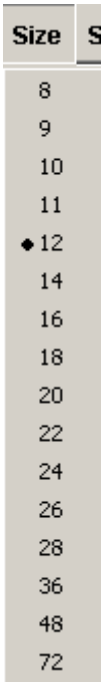
When the user clicks “Generate Report” in any mode, a properly formatted report will be created and the Report module will be opened to edit and print it. The basic report is automatically saved to the patient’s folder. Text can be added at any point in the document by clicking and typing; existing text is changed by selecting it, and typing the new text. Clicking **Save** will save the changes to the file.

New creates a blank generic report, **Delete** erases the current report, **Export** saves the report as a PDF file in the export folder (See Page 68), and **Print** sends it to the printer.
The basic editing functions are shown on the next page. The **Insert** buttons insert the selected image or the entire contents of the clipboard into the current report. Three sample reports are included at the end of the section. In the B scan report; a second image was copied from the Clipboard.



Clicking on any of the five tabs above the report window opens editing controls identical to those found in any basic text editor. The user has complete control over the appearance of the report.

Choose the font



Set font size

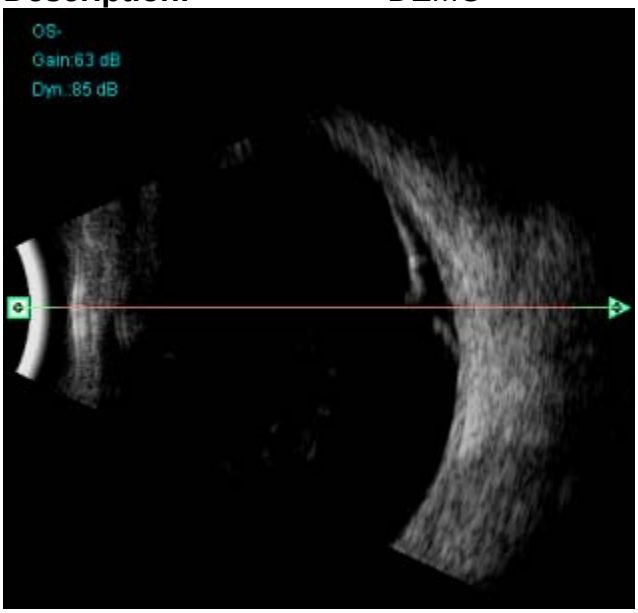
Set the style of the text

Set text alignment

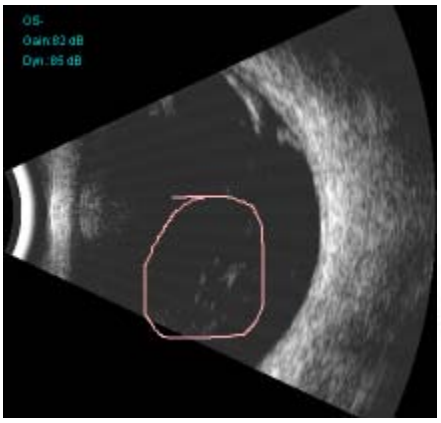
OTI Scan 3000

OTI-Scan Report

Patient Name: Retinal Tear, Vitreous Hem **Patient ID:** 03007
Date: May 21, 2003
Description: DEMO



OS

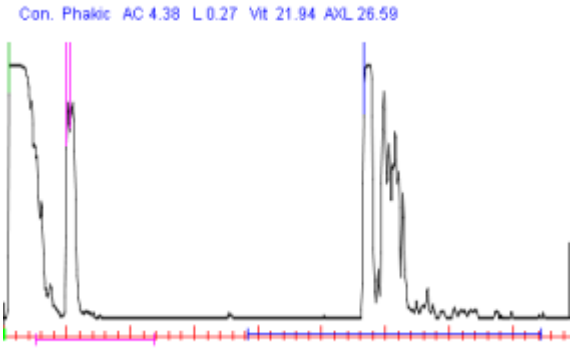


Comments: hemorrhage not clearly visible in all views

OTI Scan 3000

OTI-Scan Report

Patient Name: Intraocular, Lens **Patient ID:** HF0005
Date of Image: Jun 7, 2005
Description:



OS

Axial Length: 26.59(mm) Average: 27.11 StdDev: 0.27
Target Ametropia:0 K1: 43.2(D) K2: 42.9(D)
Contact Phakic
Vac = 1532.00 Vl = 1641.00 Vv = 1532.00

AP961L* Allergan/Ioptex
Formula: SRK-T
A: 114.5

IOL (D)	REF (D)
7.50	1.72
8.00	1.34
8.50	0.96
9.00	0.57
9.50	**0.18**
10.00	-0.22
10.50	-0.62
11.00	-1.03
11.50	-1.44

IPP601350 EUROCRYSTAL
Formula: SRK-II
A: 118.3

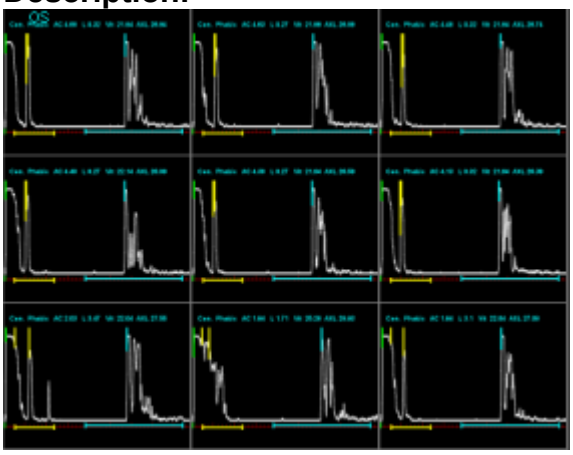
IOL (D)	REF (D)
10.50	2.08
11.00	1.58
11.50	1.08
12.00	0.58
12.50	**0.08**
13.00	-0.42
13.50	-0.92
14.00	-1.42
14.50	-1.92

Comments:

OTI Scan 3000

OTI-Scan Report

Patient Name: Intraocular, Lens **Patient ID:** HF0005
Date of Image: Jun 7, 2005
Description:



OS

Axial Length: 26.59(mm) Average: 27.11 StdDev: 0.27
Target Ametropia:0 K1: 43.2(D) K2: 42.9(D)
Contact Phakic
Vac = 1532.00 Vl = 1641.00 Vv = 1532.00

AP961L* Allergan/Ioptex
Formula: SRK-T
A: 114.5

IOL (D)	REF (D)
7.50	1.72
8.00	1.34
8.50	0.96
9.00	0.57
9.50	**0.18**
10.00	-0.22
10.50	-0.62
11.00	-1.03
11.50	-1.44

IPP601350 EUROCRYSTAL
Formula: SRK-II
A: 118.3

IOL (D)	REF (D)
10.50	2.08
11.00	1.58
11.50	1.08
12.00	0.58
12.50	**0.08**
13.00	-0.42
13.50	-0.92
14.00	-1.42
14.50	-1.92

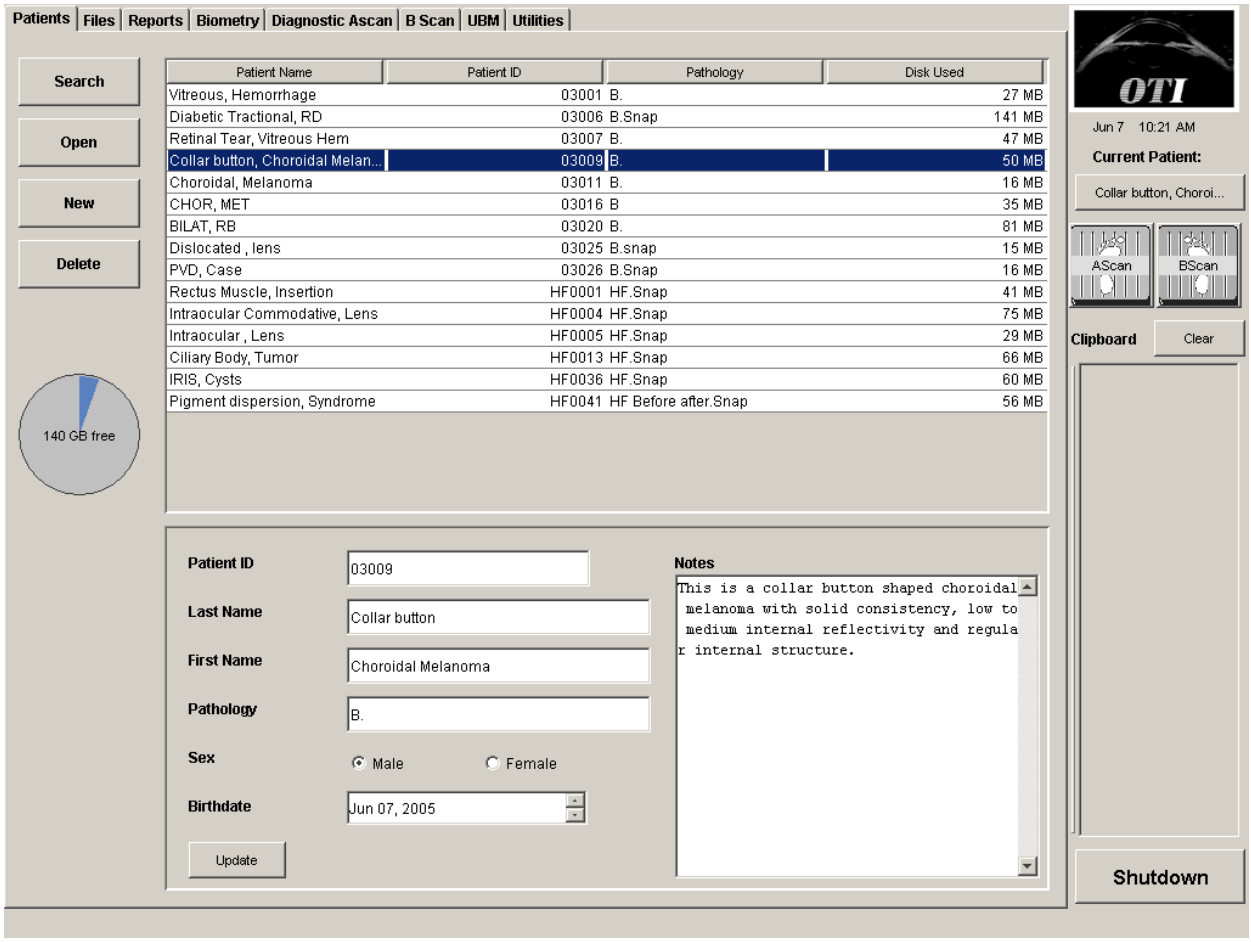
Comments:

Chapter 5
Operation: Advanced Functions

1. Patient Management

The software will start showing the Patient List, with functions for the management of patient files.

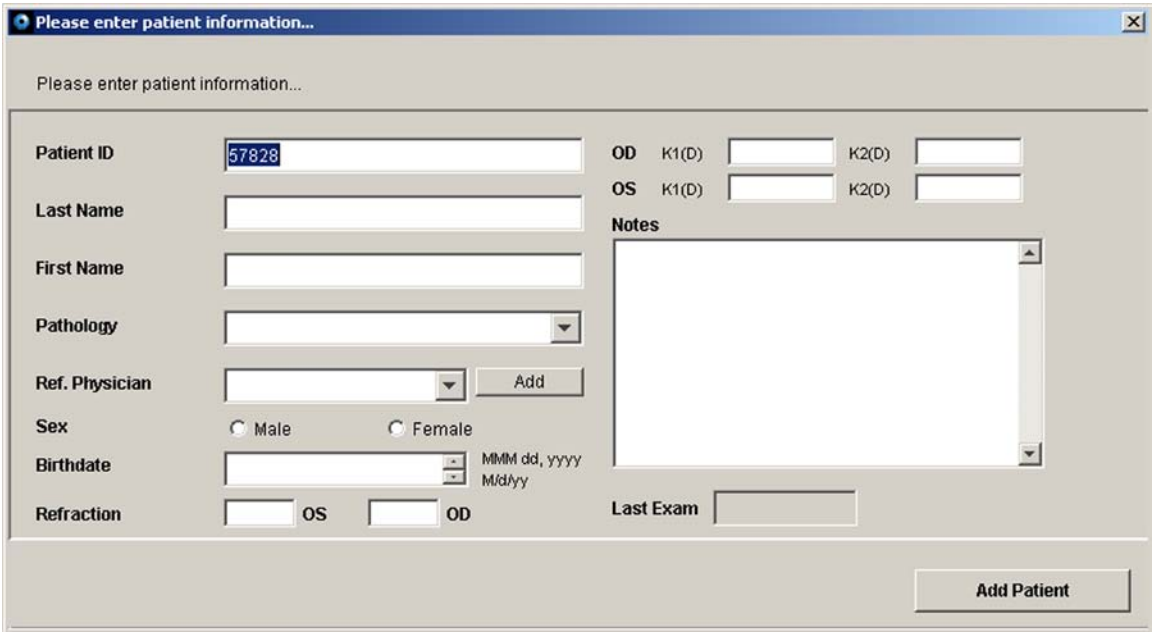
To select a patient, click on the name to highlight it. The buttons on the left side of the

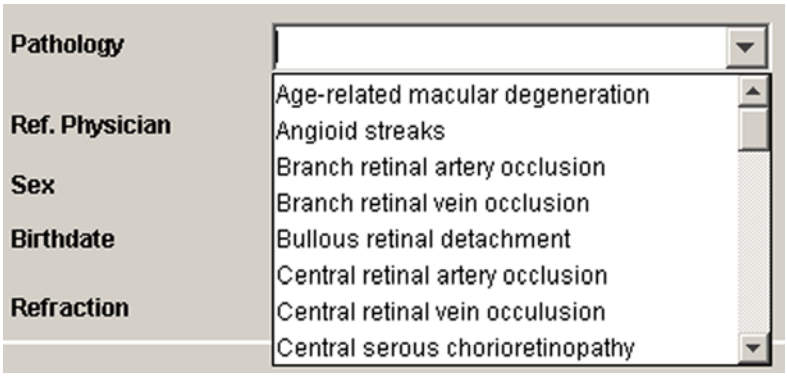


screen open the different file-management dialogs. To view the patient's files, click on the File tab, or on **Open**. Patient information and the case notes can be updated at any time by typing the new data in the appropriate field and clicking **Update**.

Click **New** to open the dialog for creating a new patient folder:

The first three lines are required information. A Patient ID is automatically generated when the dialog is opened: it should be replaced with the ID normally used in the practice.



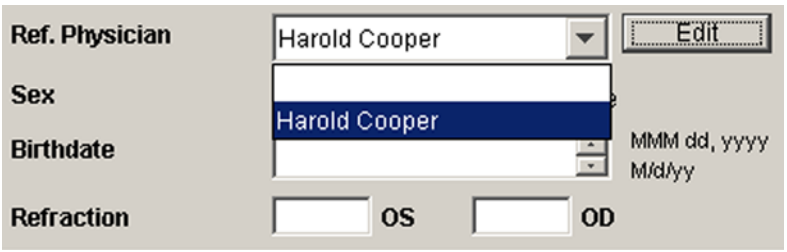


Pathology

Pathology can be entered directly in the field, or a standard description selected from the drop-down list.

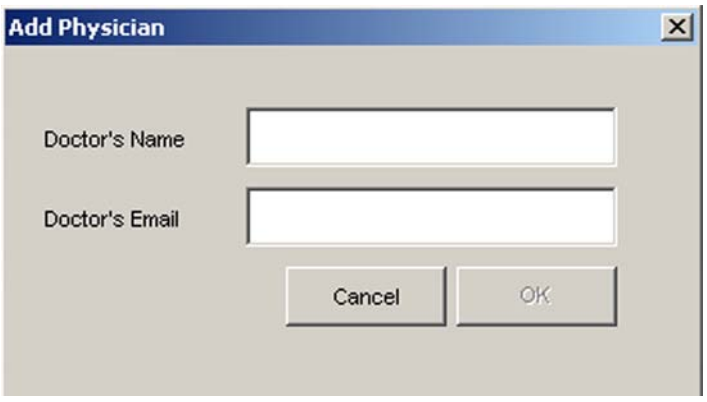
Referring Physician

The name of the referring physician can be selected from the drop-down list. New names must be added through the **Add Physician** dialog, which is opened by clicking **Add**. Edit opens the same dialog to edit the e-mail entry.



Add Physician

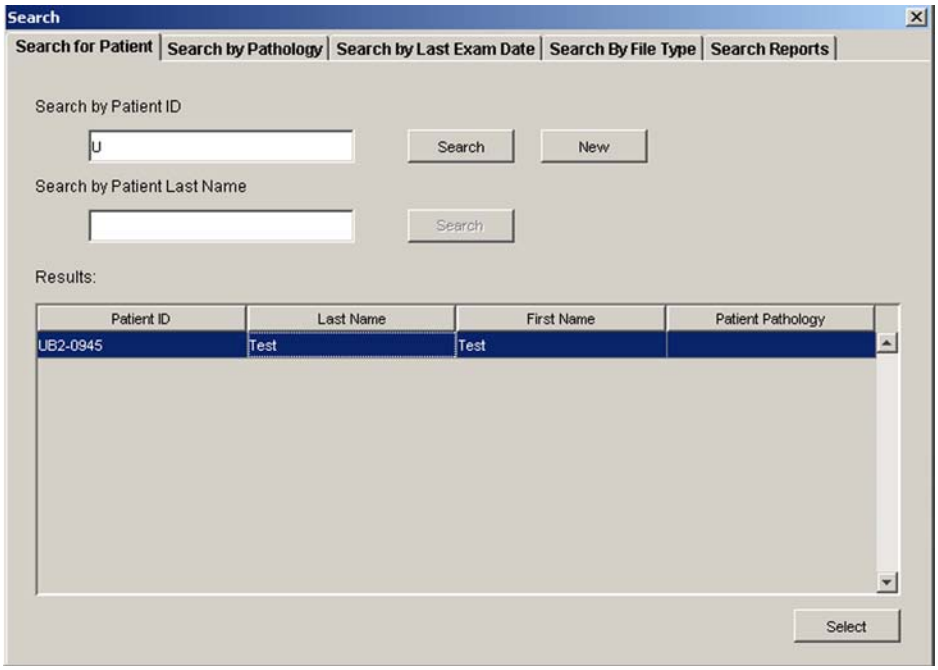
The physician name and e-mail address are entered. Once entered, the name cannot be edited. The e-mail address can be used to automatically e-mail reports to the physician



Search for Patient

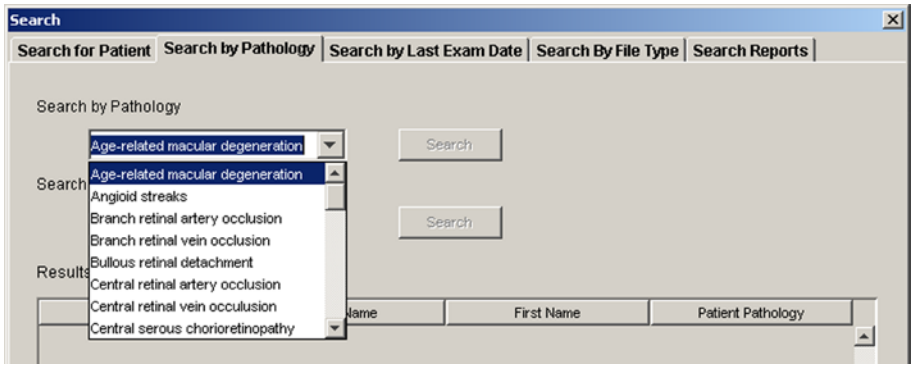
The first characters of the Patient ID or last name are entered in the search field. ID searches are case-sensitive: strings must be entered as they appear in the patient record. Clicking **Search** will list the patients matching the search parameter in the **Results*:*** box; results can be sorted by clicking on the column headers. Clicking on a patient, then **Select,** will open the patient entry.

If the patient isn't found, clicking **New** will open the New Patient dialog so that a new entry can be created.



To find a patient's file, click Search to open the Search dialog. Enter the search parameter in the correct box, and click Search to search the patient list. It is possible to search for a particular patient, for all patients with a particular pathology, for patients seen in a particular range of dates, for a particular type of saved file or for all patients with a given text saved in their exam results.

Search By Pathology

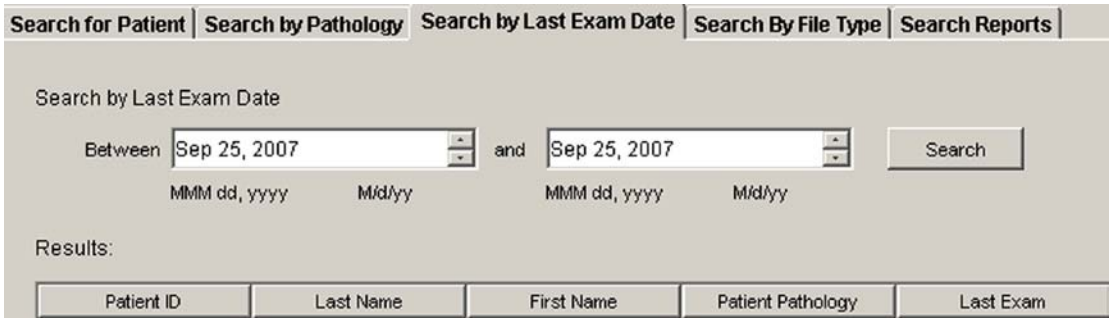


Text in the Pathology field or Notes field can be searched by entering the search string in the appropriate box.

Pathologies can also be selected from the drop-down list. Clicking Search will list the patients matching the search parameter in the Results*:* box; results can be sorted by clicking on the column headers. Clicking on a patient, then Select, will open the patient entry.

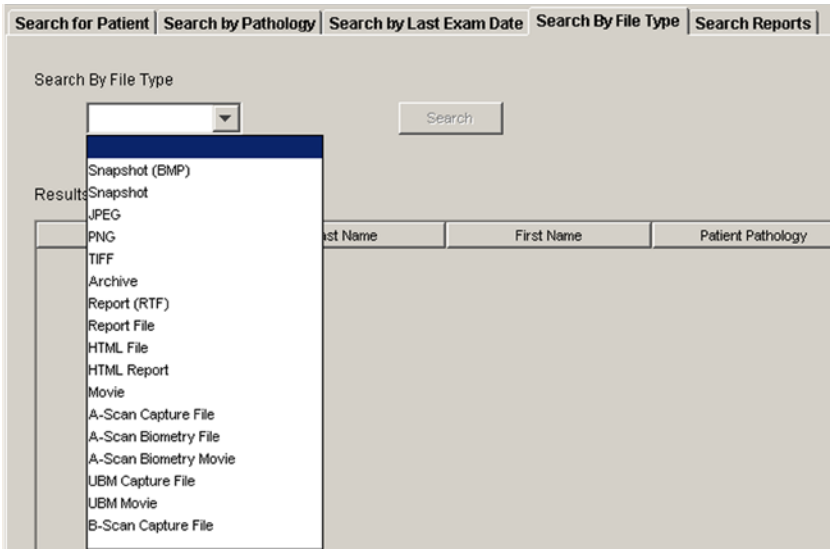
Search by Last Exam Date

Search by Last Exam Date finds patients last seen in a particular period by entering the start and end dates in either of the indicated formats. Clicking **Search** will list the patients matching the search parameter in the **Results***:* box; results can be sorted by clicking on the column headers. Clicking on a patient, then **Select,** will open the patient entry.



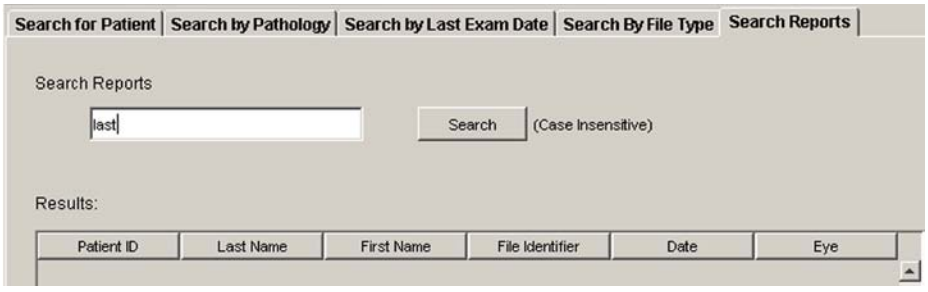
Search by File Type

Search by File Type finds all patients with particular files in their folders. Clicking Search will list the patients matching the search parameter in the Results Box. Results can be sorted by clicking on the column headers. Clicking on a patient, then Select, will open the patient entry.

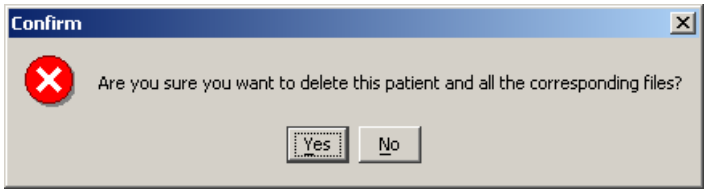


Search Reports

Any text string in a saved report can be entered in the search field. Searches in this section are not case-sensitive. Clicking **Search** will list the patients matching the search parameter in the **Results*:*** box; results can be sorted by clicking on the column headers. Clicking on a patient, then **Select,** will open the patient entry.

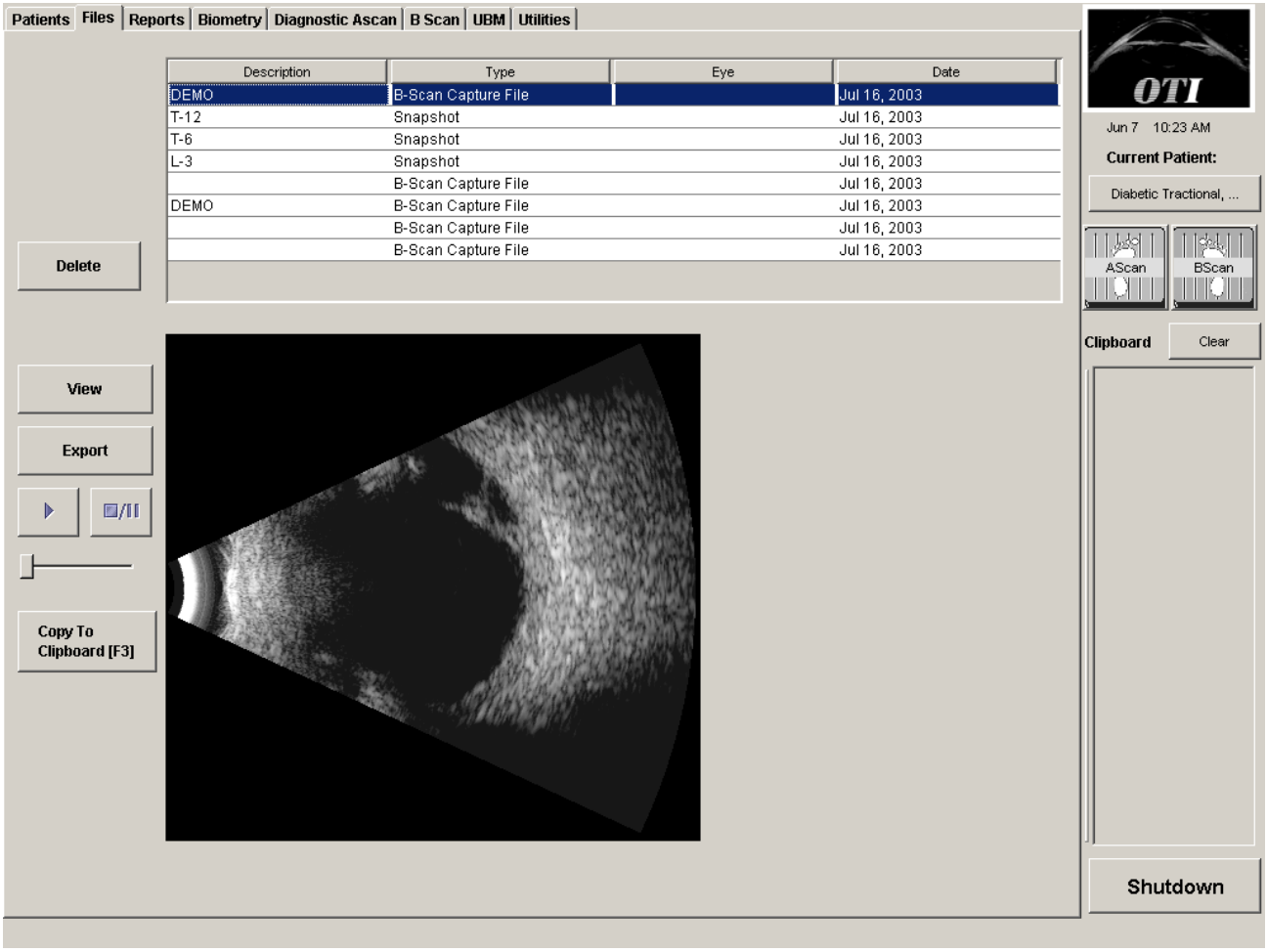


Clicking Delete will delete the selected patient, if the user clicks Yes in the confirmation dialog:

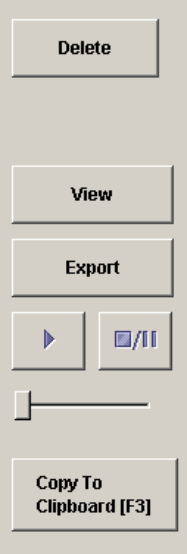


1. Files

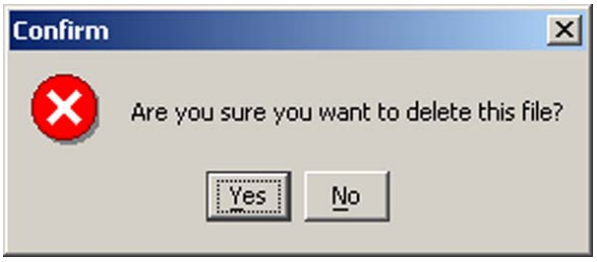
When a Patient folder is opened, a list of the files saved for that patient is displayed.



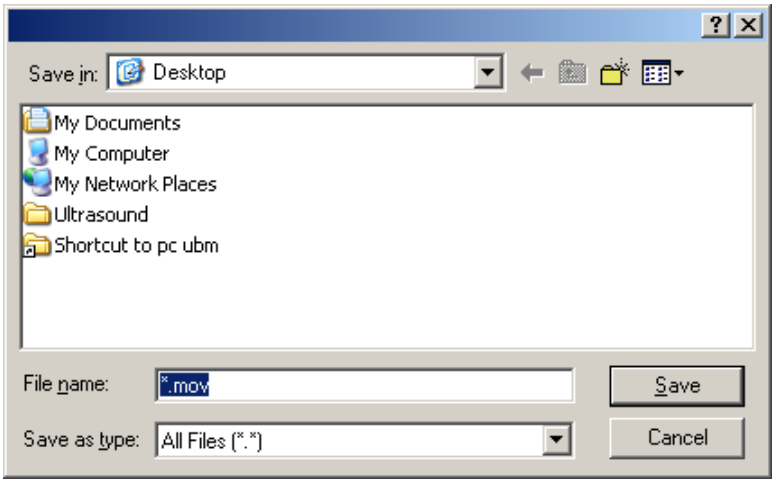
When an image file has been selected in a Patient Folder, a preview window opens with basic information and controls. The image can be reviewed to ensure the correct file is selected. (See Page 81 for more information on the Snapshot controls)



The controls beside the list will open, export, preview or delete the selected file. When the clipboard is enabled, **Copy to Clipboard** will copy the current frame to the clipboard for use in a report.



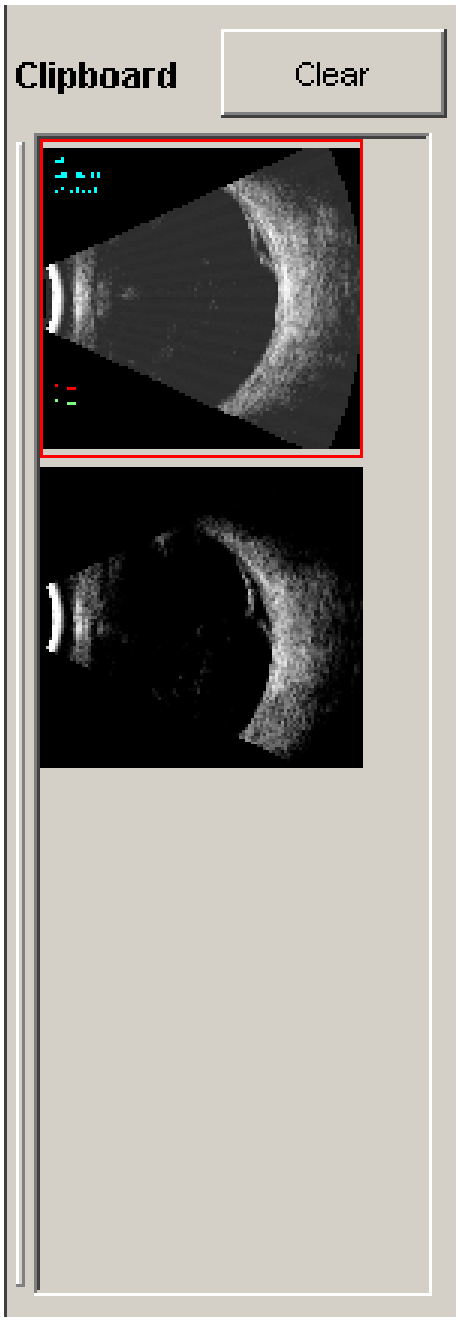
Selecting Delete will open the confirmation dialog.



Selecting **Export** will open the dialog for selecting a destination for the exported file. Any volume mounted by the Windows file system may be used.

Once the desired location is highlighted, clicking **Save** will copy the file.

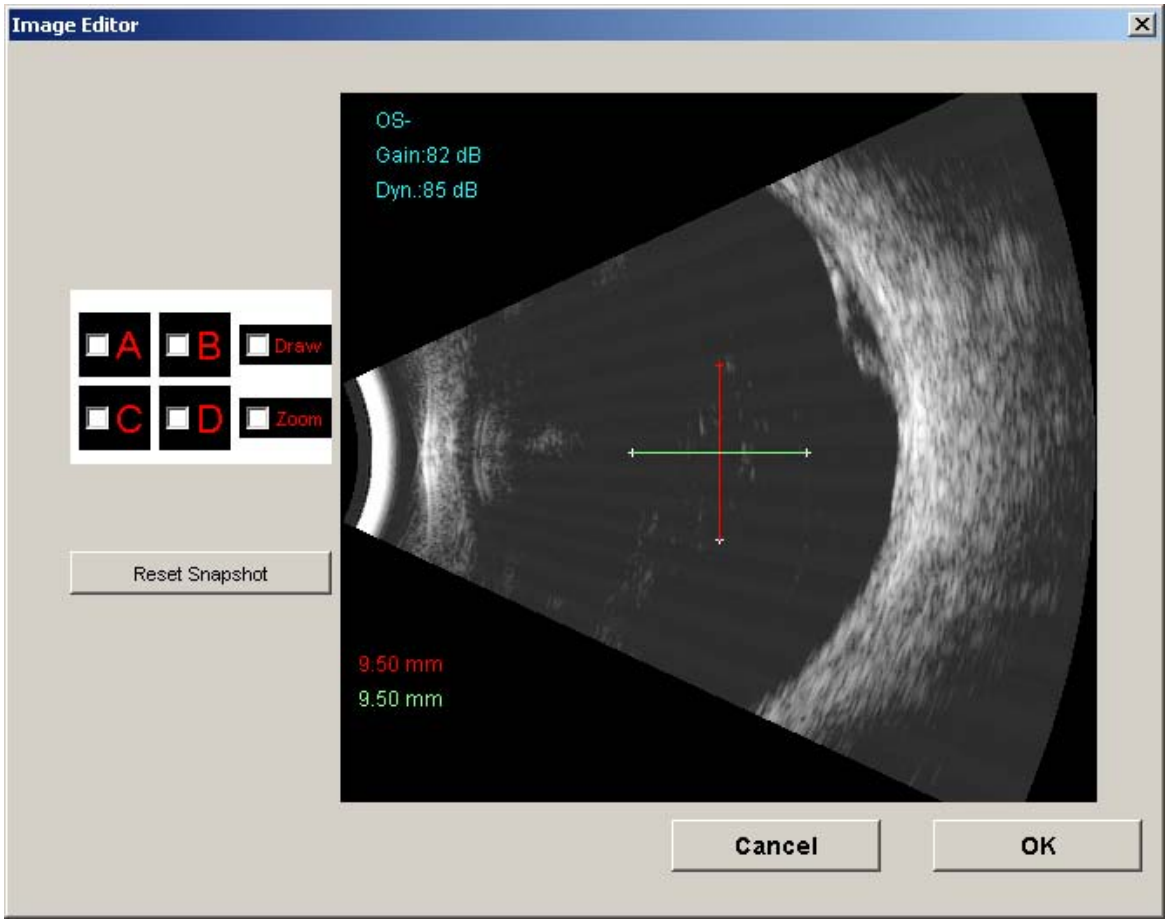
2. The Clipboard



The clipboard is used to store individual B scan frames, A scan curves and images recovered from Snapshot files, for inclusion in a report. The data can come from alternative views of the same patient, for a longitudinal study or to gather all available data on a complex case, or, from different patients, for lateral studies.

Images are saved on the clipboard by clicking **Copy to Clipboard** when the button is visible. **Clear** will erase the contents of the clipboard.

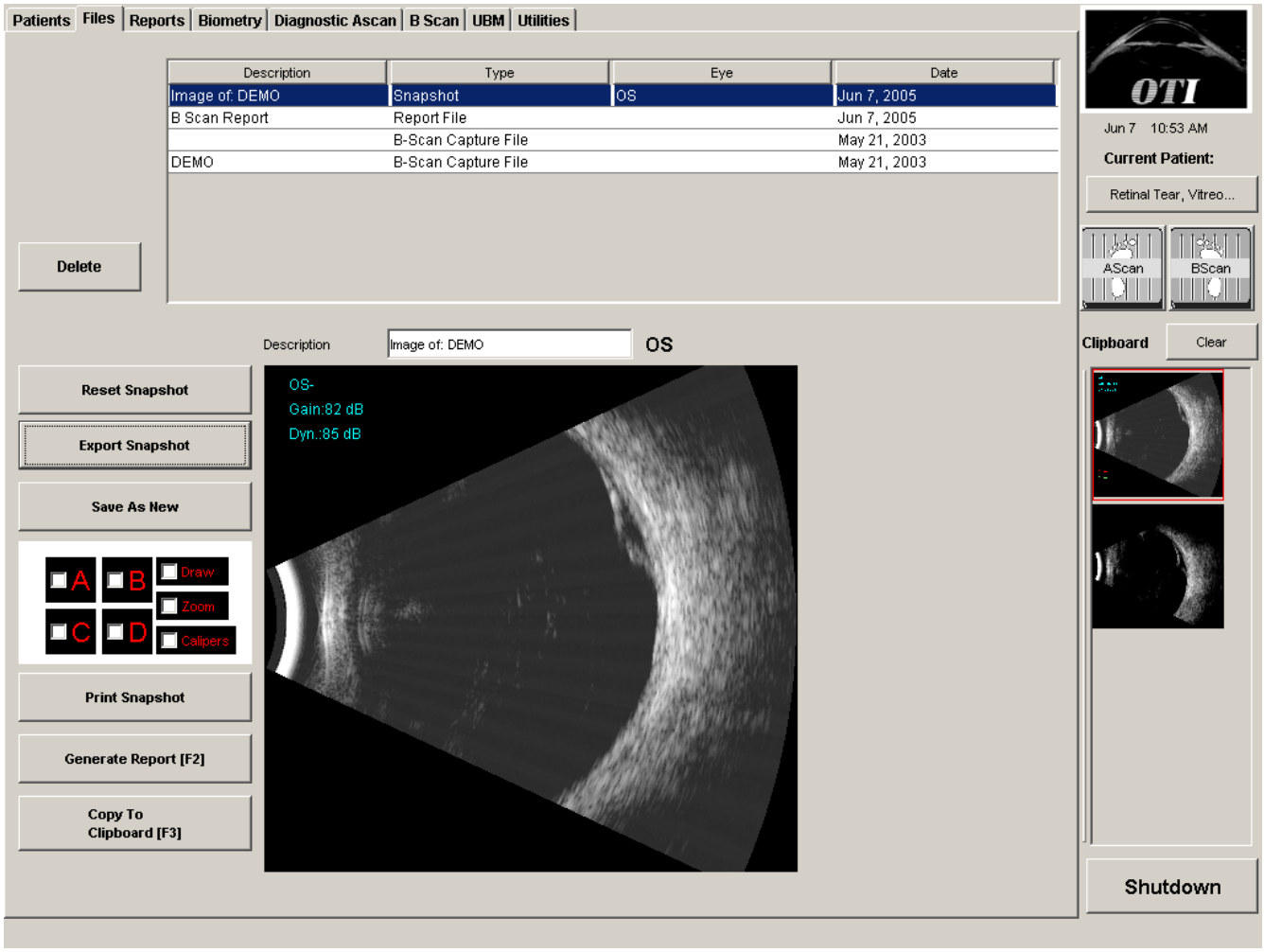
An image is selected by clicking on it. Double-clicking will open the annotation editor.



The clipboard image editor can be used to insert markers in an image before it is included in a report. Four pointers can be placed and arbitrary outlines drawn. The image can also be zoomed 2X.

3. Snapshots

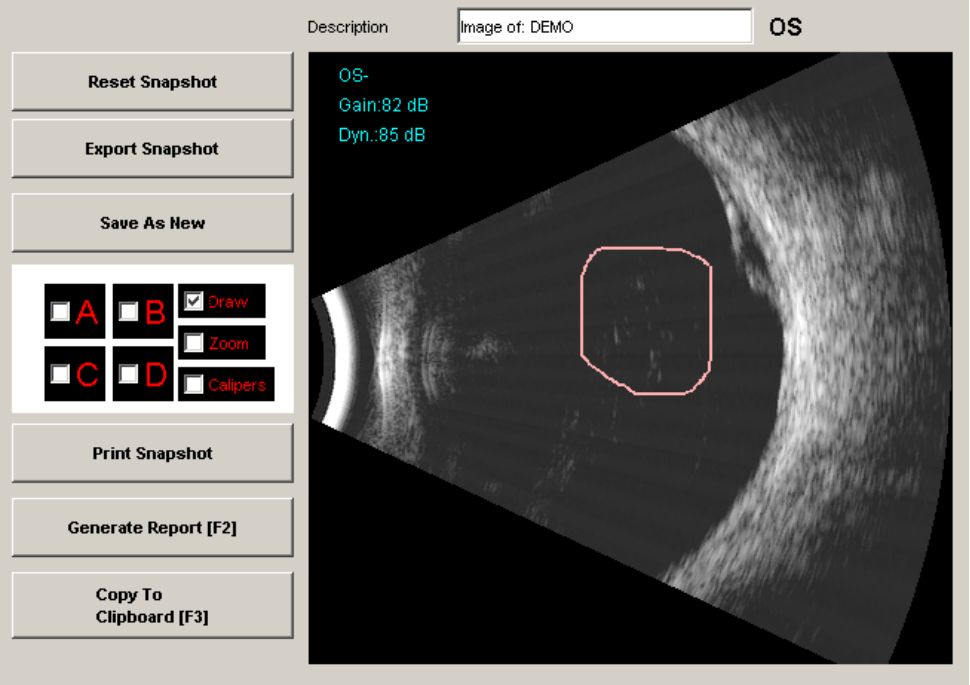
Snapshots are the only files that are edited directly in the Files view.



Once a snapshot has been marked up, it can be exported as an image file, printed, used to generate a report or copied to the clipboard for inclusion in another report.

The mark-up information will not be saved automatically. Click on **Save As New** to save the changes to a new file.

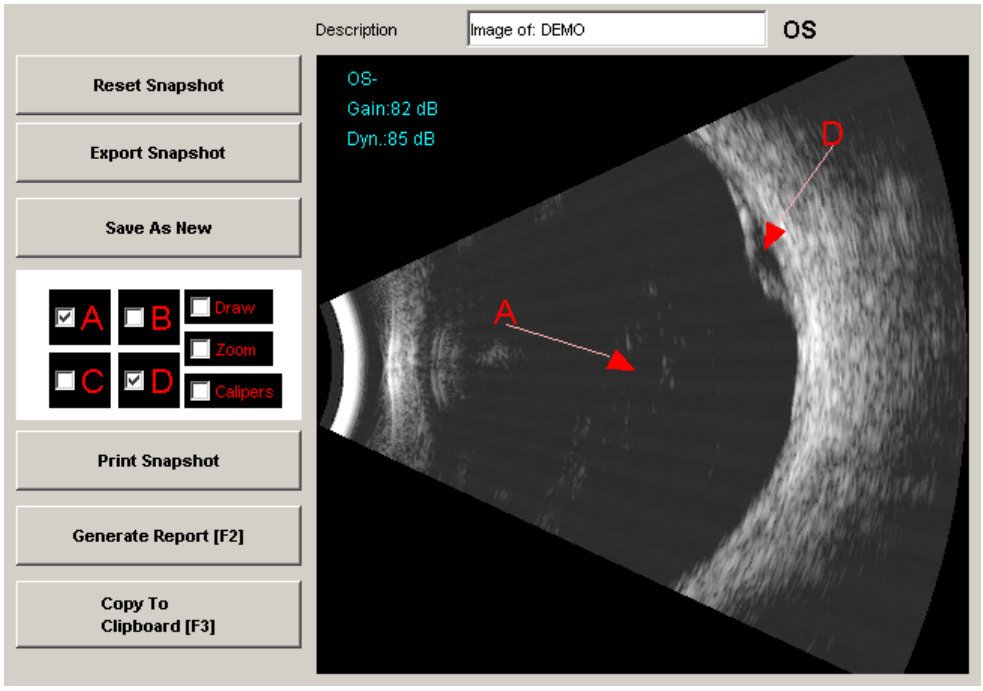
Clicking on **Reset Snapshot** clears the changes.

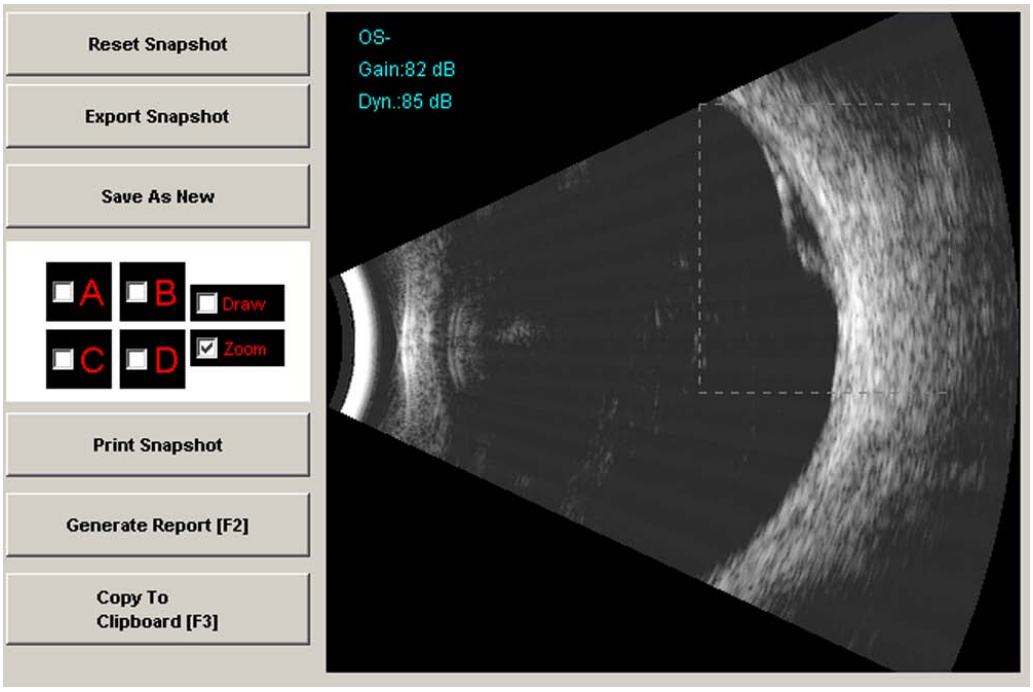


To enlarge the image, click **Zoom**. Clicking on the image and dragging the mouse will outline a rectangular area that will be enlarged. The enlargement depends on the area selected, but scaling the image too much will not give a usable enlargement.

To highlight a region of interest, click on **Draw**. Place the cursor on the image, then click on the mouse and drag the cursor to trace the path.

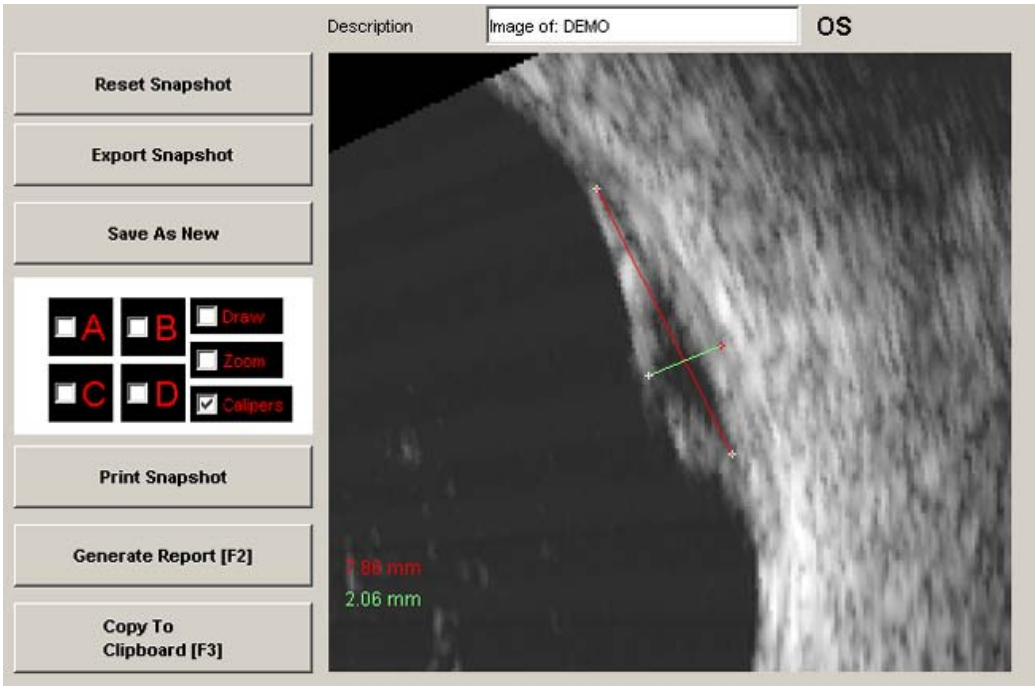
Clicking on **A**, **B**, **C** or **D** creates a pointer that can be positioned by clicking and dragging on the arrowhead or letter



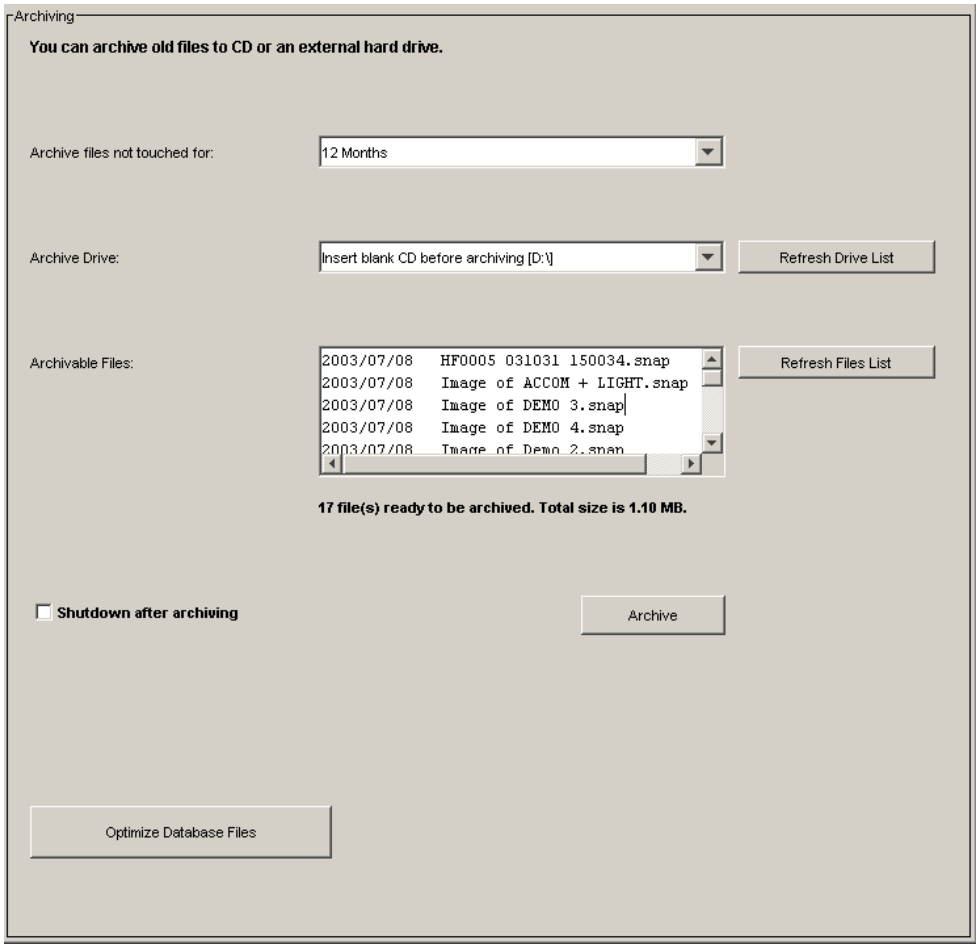


The **Caliper** functions in the same way as the calipers in B scan

(This image was zoomed before



5. Archiving Data



Data must be archived to ensure that it is not lost in the event of a system failure. Removing infrequently viewed files from the disk will also improve performance and free space. B mode movies can be very large, and the user can run out of disk space unexpectedly if archiving is not kept up to date. The user can select the period that files can be left unused before being marked for archiving.

The normal medium for archives is CD-R, but any external drive recognized by Windows may be used.

Refresh Drive List can be used to locate a drive that is not recognized automatically, and add it to the list of Archive drives.
The user determines how long files may be left unused by selecting the period from the ***Archive files*****:** pick list. If more than one drive is available for archiving, a similar list can be opened beside ***Archive Drive:***

The system can be left to complete the archive operation and shut itself off if the **Shutdown…** box is checked. Note: the files to be archived must fit on one disk for the operation to complete.

When all the options are selected, click on **Archive** to start the process.

Chapter 6
Background, Theory and Formulas

1. AXIAL LENGTH MEASUREMENTS

Steps for Accurate Biometry
IOL Power Calculations

BIOMETRY-AXIAL LENGTH MEASUREMENTS:

- **Scan Capture:** Capture at least 6-10 measurements (scans); review each of the captured images. Select only the scans with a good echo pattern and delete the rest. At least 3–4 good scans with an Axial Length standard deviation (SD_{AL}) of 0.1 or lower should be saved and used for IOL calculations. (The variation of the axial length, from the highest to the lowest, of the scans should be not more than 0.1-0.2mm.)

  The software also indicates the anterior chamber depth standard deviation (SD_{ac}). This information indicates to the user the degree of variation in the anterior chamber depth (AC) measurements. Large variations in AC measurements indicate compression of the cornea and/or off-axis positioning of the probe.

- **Selecting the Best Scans:** review each scan; verify the position of the 4 markers. Each marker should be placed at the top of the echo. Observe the Retinal echo; it should be sharp (90 degree from the baseline) with minimum amplitude height of 70% of the corneal echo.

  The Anterior Lens and Posterior Lens echoes should also have a height of at least 70% of the corneal echo. Note: in cases of dense cataract, the posterior lens echo will be lower than the Anterior Lens echo due to absorption of sound by the opaque lens.

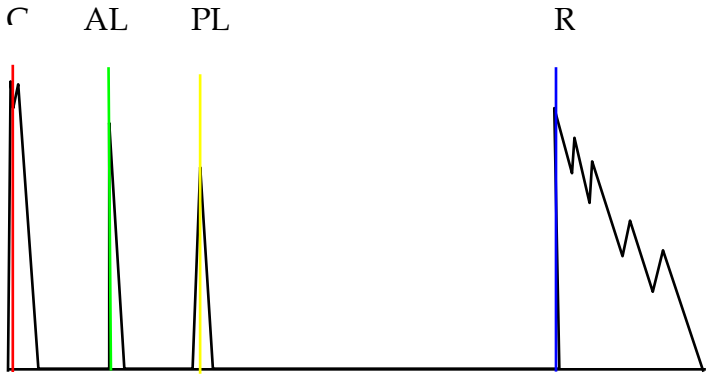
  Pay attention to the Anterior Chamber Depth (ACD). The operator should save the measurements with longest ACD. These are usually the measurements where there was minimum corneal compression. (An off-axis probe position may also produce a longer ACD, however in this case the retinal echo will be of poor quality).

- **Dense Cataracts:** In a dense cataract, additional low echoes might appear between the Anterior Lens and the Posterior Lens echoes. Some reverberations of the Anterior and/or posterior Lens echoes might be present in the vitreous when the cataract is very dense especially when higher Gain is needed in order to capture the retinal echo. **Note**: make sure that the markers are positioned on the principal Anterior and Posterior lens echoes and not on the repetitions in order to avoid error in measurements. In a very dense cataract the user may need to increase the gain setting in order to achieve good retinal echo. This is due to the higher absorption of sound in the dense lens.

- **Silicone Oil-filled eye:** In the case a of silicone oil-filled eye, the tissue velocity must be corrected.

If oil was placed in the vitreous and the posterior capsule is intact, replace the Vitreous Tissue velocity (1532 m/sec) with 980 m/s in the User Screen in the Biometry X-Mode. If the lens was also removed, you must replace the lens tissue velocity of 1641 m/s with the velocity in silicone oil (980 m/sec.). If the Anterior chamber is also filled with oil, the correct velocity must be typed in place of 1532 m/s, which is the tissue velocity in the Aqueous.

– **Pseudo-phakic eyes:** when measuring eyes that have previously undergone cataract surgery, the tissue velocity must be corrected for the implanted IOL. The tissue velocity for PMMA IOL is 2718 m/s, for Acrylic IOL is 2120 m/s and for Silicon IOL its 1049 m/s. Please note that these values are averaged between different IOL manufacturers. Small variations of IOL tissue velocity between different manufacturers will not effect the reading substantially. If the user is not sure what kind of IOL was implanted, an observation of the retinal echo distance may help.



Good scan, markers placed at the peak of each echo

Poor scan: off-axis scan, AL echo too low, retina echo too low, front of retina not perpendicular to the base line, retinal marker off to the right.

If either the AL or Retinal echo is too low, it is an indication that the probe is off the visual axis. The axial length may be either too short or too long.

Note: The first marker (Cornea) will be to the right of the initial peak, which is the front of the transducer. The tip of the probe will be to the right of this.

IOL Formulas

VARIABLES USED:

Variables in any formula:

AL: Axial length.

K: Averaged dioptric power of the cornea = (K1 + K2 / 2)

R: Corneal curvature in mm = 337.5 / K (K in Dioptres)

ACD: Post-Operative Anterior Chamber Depth,

S.R.K.- T:

Retinal thickness: Rethick = 0.65696 - 0.02029 x AL

Lc = AL except if AL > 24.2, Lc = -3.446 + (1.716 × AL) - (0.0237 × AL^2)

K = 337.5 / R

R = 337.5 / K

C1 =-5.40948 + 0.58412 ×Lc + 0.098 × K

Rc=[R^2 -$(C1)^2$/4]

If Rc < 0 then Rc = 0

$$C2 = R - \sqrt{Rc}$$

ACD = 0.62467 × A - 68.74709, where A= SRK Constant

ACDE = C2 + ACD - 3.3357

n1 =1.336

n2 = 0.3333

LO = AL + Rethick = 0.97971 × AL + 0.65696

S1 = LO-ACDE

S2 = n1x Kd - n2 × ACDE

S3 = n1 x Kd - n2 x× LO

S4 =12x83 + LO×Kd

S5=12xS2 + ACDE ×Kd

$$REF\_X = \frac{1336 \times S3 - IOL \times S1 \times S2}{1.336 \times S4 - 0.001 IOL \times S1 \times S5}$$

$$IOL\_FOR\_TGT = \frac{1336(S3 - 0.001 REFt \times S4)}{1.336 S4 - .0001 REFt \times S5}$$

S.R.K.-II :

EMMETROPIC POWER:

P = A - 2.5AL - 0.9K + C

C = Correction to the first S.R.K. formula where C=0.

If AL < 20 mm then C = + 3

If 20 <= AL < 21 then C = + 2

If 21 <= AL < 22 then C = + 1

If 22 <= AL < 24.5 then C = 0

If AL >= 24.5 then C = - 0.5

SRK-II: AMETROPIC POWERS :

with: P = Emmetropic power

I = Desired implant power

Rt = Target Refraction

Rf = Refraction factor.

Refraction = Vs (I) :

Rt=(P-I)/Rf , where Rf=1.25 if P> 14

Rf=1 if P $\leq$ 14

Implant = Vs (Rt):

I = P - (Rt$\times$Rf), where Rf = 1.25 if P > 14

Rf=1 if P $\leq$ 14

BINKHORST II:

VARIABLES

LB : AXIAL LENGTH CORRECTED FOR BINKHORST II.

Lb= LA+0.1984 mm

ACD-B : ANTERIOR CHAMBER CORRECTED FOR POSTERIOR CHAMBER LENSES

If Lb < 26 then ACD-b = ACD x (LA / 23.45)

If Lb >= 26 then ACD-b = ACD x (26 / 23.45), or ACD-b =1.1087 x ACD

R: Cornea curvature in mm = 337.5 / K (K in Diopters)

Ref: Target Refraction

Lb: Corrected Axial length.

AC: POST OPERATIVE ANTERIOR CHAMBER

AC = ACD for Anterior Chamber lOLs

AC = ACD-b for Posterior Chamber lOLs.

FORMULA GIVING THE IMPLANT VALUE VERSUS THE DESIRED REFRACTION : REF

IOL = Vs (Ref) if Ref =0 IOL= IOLem (emmetropia)

$$IOL = \frac{1336\,[1.336\mathrm{R} - 0.3333\mathrm{Lb} - 0.001\,\mathrm{Ref}\ (16.032\mathrm{R} - 4\mathrm{Lb} + \mathrm{Lb}\times\mathrm{R})\,]}{(\mathrm{L} - \mathrm{AC})\,[1.336\mathrm{R} - 0.3333\mathrm{AC} - 0.001\,\mathrm{Ref}\ (16.032\mathrm{R} - 4\mathrm{AC} + \mathrm{AC}\times\mathrm{R})])}$$

1336 [1.336R - 0.3333Lb - 0.001 Ref (16,032R - 4Lb + Lb.R)]

FORMULA GIVING THE REFRACTION VERSUS THE DESIRED IMPLANT IOLAM

Ref = Vs (IOL)

$$\mathrm{Ref} = \frac{1336\left[1.336R - 0.33L\right] - IOL[Lb - AC][1.336R - 0.3333AC]}{1.336[16.032R - 4L + L\times R] - 0.001IOL[Lb - AC][16.032R - 4AC - AC\times R]}$$

HOLLADAY:

VARIABLES :

R: Cornea curvature in mm = 337.5 / K (K in Diopters)

R_{ef}: Target Refraction

L_H - AXIAL LENGTH CORRECTED FOR HOLLADAY.

L_h = AL + 0.200 mm

SF - SURGEON FACTOR: SPECIFIC FOR HOLLADAY FORMULA.

SF = (A x 0.5663) - 65.60 where A is the SRK Constant

ACH - ANTERIOR CHAMBER CORRECTED FOR HOLLADAY.

Rag = R, except that if R < 7mm then Rag = 7 mm

AG = (12.5 / 23.45) AL , except that if AG > 13.5 then AG = 13.5 mm

$$ACD = 0.56 + Rag - \sqrt{Rag^2 - AG^2/4}$$

A_{Ch} = ACD + SF

FORMULA GIVING THE IMPLANT VALUE VERSUS THE DESIRED REFRACTION (OR AMETROPIA): REF

IOLam = Vs (Ref)

if R_{ef} =0 IOLam = IOLem (emmetropia)

$$IOLam = \frac{1336[1.336R - 0.3333L_h - 0.001R_{ef}(16.032R - 4L_h + L_h \times R)]}{(L_h - A_{Ch})[1.336R - 0.3333A_{Ch} - 0.001R_{ef}(16.032R - 4A_{Ch} + A_{Ch} \times R)])}$$

FORMULA GIVING THE REFRACTION VERSUS THE DESIRED IMPLANT: IOLam

R_{ef} = Vs (IOLam)

$$R_{ef} = \frac{1336[1.336R - 0.33L_h] - IOLam[L_h - A_{Ch}][1.336R - 0.3333A_{Ch}]}{1.336[16.032R - 4L_h + L_h \times R] - 0.001IOLam[L_h - A_{Ch}][16.032R - 4A_{Ch} + A_{Ch} \times R]}$$

HOFFER-Q:

VARIABLES :

P: Implant POWER (D)

R : Refractive error at corneal plane (D).

Rx: Desired ametropia : Refractive error at spectacle (D).

K : Average Keratometry (D)

CD: Corrected Chamber Depth (mm).

ACD: Anterior chamber depth from the personalized IOL User file.

AL: Axial Length (mm)

CORRECTED CHAMBER DEPTH :

If AL<=23, M=+1 and G=28

If AL>23, M=-1 and G=23.5

If AL>31, AL=31

If AL<18.5, AL=18.5

$$CD = ACD + 0.3(AL - 23.5) + \tan^2 K + 0.1M(23.5 - AL)^2 \times \tan[0.1(G - AL)^2] - 0.99166$$

EMMETROPIA POWER :

R=Rx/(1-0.012Rx)

P = [1336 / (AL - CD - 0.05)] - {1.336 / [(1.336 / (K + R)) - ((CD + 0.05) / 1000)]}

FORMULA GIVING THE REFRACTION (RX) VERSUS THE DESIRED IMPLANT: IOLAM

Rx = vs (IOLam)

$$R = \frac{1.336}{\frac{1.336}{1336/(AL - CD - 0.05) - IOLam} + \frac{CD + 0.05}{1000}} - K$$

Rx=R/(1 +0.012R)

SPECIAL CONSIDERATIONS FOR UNUSUAL CASES

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Concurrent Astigmatic Keratectomy:

- Subtract 0.25D from the pre-op Ks for every diopter of the astigmatism to be corrected.

After Refractive Keratectomy:

- Refractive History Method:

Subtract the change at the corneal plane induced by the refractive surgery from the average corneal power measured before the Keratectomy.

- Contact Lens Method
- Adjustment Method:

subtract 0.25D from the Ks for every diopter of myopia corrected.

PIGGYBACK IMPLANTS:

$$\text{(+) Refractive Error} = \frac{\text{Error (+)}}{0.03\ (138.3\text{-A})} - 0.5$$

$$\text{(-) Refractive Error} = \frac{\text{Error (-)}}{0.04\ (138.3\text{-A})} - 0.5$$